OBTAINING CONSENT FROM PATIENTS – THE GAP BETWEEN LAW AND PRACTICE

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An Academic Project submitted in partial fulfillment for the Degree of Master of Laws
2008/2009

ABSTRACT

The doctrine of informed consent being an important communication tool for medical treatment administered towards a patient has been a continuing interest throughout the years. When we visit the doctor, we would want to be told as to what is wrong with us and how we can get treated. Doctors always have a strong hold on patients when the patient consents to the medical treatment.

This research paper addresses the position of the doctrine of informed consent both in law and practice in considerable detail, which helps determine whether patient autonomy has been achieved. This paper highlights the duty of disclosure of information of a doctor or physician to their patient both in law and practice as well as the processes, which are involved in obtaining the said consent from a patient. It is important that a patient should consent to the treatment only after having understood to the nature of the treatment. The recent cases of *Chien Tham Kong v Excellent Strategy Sdn Bhd & Ors* [2009] 7 MLJ 261 and *Dr Ismail Abdullah v Poh Hui Lin* [2009] 7 CLJ 167 have also been considered on the issue of disclosure as being an ongoing problem in practice. Lastly, interviews were conducted with doctors/ physicians and patients to explore the application and understanding of this doctrine in practice.

ABSTRAK

Sejak kebelakangan ini, keizinan oleh pesakit untuk dirawat merupakan satu doktrin komunikasi yang amat penting dalam bidang perubatan. Semasa melawat doktor untuk rawatan, seorang pesakit ingin tahu tentang penyakit yang dihadapinya dan rawatan yang terlibat. Seorang doktor main peranan yang penting untok mendapatkan keizinan dari pesakit.

Kertas penyelidikan ini membincang dari segi undang-undang kewajipan seorang doktor untuk memberi semua maklumat tentang penyakit dan rawatan kepada seorang pesakit serta proses yang terlibat. Adalah amat penting untuk seorang pesakit memberi keizinan hanya selepas memahami segala keterangan yang diberi sebelum menjalani sebarang rawatan. Kes-kes terkini seperti *Chien Tham Kong v Excellent Strategy Sdn Bhd & Ors* [2009] 7 MLJ 261 dan *Dr Ismail Abdullah v Poh Hui Lin* [2009] 7 CLJ 167 dibincang dalam kertas ini. Akhir sekali, temuduga telah diadakan dengan beberapa orang doktor dan pesakit untuk mendapat maklumat tentang penggunaan dan permahaman doktrin ini.

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LIST OF ABBREVIATIONS

AC	Appeal Cases
All ER	All England Law Reports
ALR	Australian Law Reports
AMR	All Malaysian Reports
Cal. 3d	California Reports Third Series
CA	Court of Appeal
CLJ	Current Law Journal
CLR	Commonwealth Law Reports
DLR	Dominion Law Reports
Ed.	Edition
F. 2d	Federal Reporter, Second Series (USA)
FLR	Family Law Review
Ibid	in the same place
Id	the same
LR	Law Review Reports
MLJ	Malayan Law Journal
NE	North Eastern Reporter (USA)
P.	Pacific Reporter
P 2d	Pacific Reporter, Second Series
QB	Queen's Bench (Law Reports)
SASR	South Australian State Reports

SC	Session Cases (Scotland)
WLR	Weekly Law Reports

CHAPTER 1

INTRODUCTION

1.1 The nature and scope of consent

At one time of another each of us will experience some contact with the orthodox medicine or rather supernatural powers[1]. The medical profession has since the early days conducted itself with a high level of ethical behaviour that has earned the trust of patients. During that time very little attention was paid to the need to understand the doctor's views about his diagnosis and proposed treatment. This was mainly due to the ignorant attitude of a layman, difference in culture and tremendous amount of trust being placed by a patient on the one person whom they regarded knew best, that is, their doctor. The patient was usually humble, undemanding and uninvolved with their treatment. The doctors, thus, adopted the authoritarian approach until the middle of the twentieth century, even in countries like Malaysia.

As of late, there has been tremendous implication around the world with regards to the credibility of the medical profession especially with regards to the importance of the doctrine of informed consent in the delivery of health care. With the advancement of complex technology, and more advanced and educated population, people have become more conscious and aware about their medical rights. Over the years, the trend shifted from cases of battery towards the value of patient autonomy in cases of informed consent.

As a result there has been an increase in the number of cases in medical negligence,[2] which is fault-based.[3] Each year about 2,000 to 4000 deaths occur in Malaysia due to medical negligence and many of these cases are unreported mainly because some are settled out of court and others may be ignorant of their rights or too poor to afford litigation[4]. In 2002, the Malaysian population was only 24 million and as at July 2008, it has reached 25,274,32 million[5]. There are about 214 private hospitals and 118 government and 7 special institutions in the country.[6]

1.2 Historical development of informed consent

Informed consent in research has its own unique history and varies from country to country as to its legal requirements. This goes way back in the 1930s in the United States, when courts upheld the importance of knowledgeable consent in medical research. The phrase "informed consent was first coined during the Nuremberg Trials where Nazi physicians were charged with conducting human experiment in German concentration camps[7] that led to the creation of ethical codes for research, including informed consent.

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[2] *News Straits Times*, Thursday, July 24, 2008. See post, Appendix 1. *The Sun*, Wednesday, May 14, 2008. See post, Appendix 2.

[3] *s30 Medical Act 1971* imposes disciplinary punishment.

[4] Prof Dr Ali Mohamad Matta, *Issues in Medical Law and Ethics,* (December 2003), Medical Law and Ethics Unit, Law Centre, Ahmad Ibrahim Kulliyah of Laws, IIUM Malaysia, p.21.

[5] CIA, *The World Factbook: Malaysia* (Available at cia.gov/library/publications/the-world-factbook/geos/my.html. Last downloaded on 20 October 2008).

[6] Under the Ninth Malaysian Plan (2006-1010).

[7] The Nuremberg Code (1947). The person must have a legal capacity to give consent, should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud,

It stated that the voluntary consent of the human subject is absolutely essential. From the international scene, there has been trace of development of the doctrine of informed consent from the Hippocratic Oath[8] to the Declaration of Geneva[9] as well as the World Medical Association International Code of Medical Ethics.[10] Article 8(1) of the European Convention of Human Rights, which states that a patient's right would be an aspect of their right privacy.[11] However, it is believed today that the Declaration of Helsinki originally promulgated in 1964, has lost much of its relevance to research ethics. One reason being that it creates an illogical distinction between therapeutic and non-therapeutic research.[12] Another flaw is that it is out of touch with current ethical thinking on placebo trials, which has profound implications for research in developing countries. In other words, this Article created significant barriers to developing new therapies. Only in the last decade has informed consent become central to the medical practice in the United States and in Europe.

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deceit, duress, and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. The principles under the Code have been embodied in various International Codes of Conduct.

[8] Hippocratic Oath –Classical version (www.pbs.org/wgbh/nova/doctors/oath_classical.html; Last downloaded on 10 October 2008).

[9] The 10 commandments were adopted in Sept.1948 through the Declaration of Geneva by the World Medical Association, later known as the Physician's Oath.

[10] Adopted by the 3rd General Assembly of the World Medical Association, London, England, October 1949 and amended by the 22nd World Medical Assembly Sydney, Australia, August 1968 and the 35th World Medical Assembly Venice, Italy, October 1983 and the WMA General Assembly, Pilanesberg, South Africa, October 2006.

[11] Similarly, this can also be seen Declaration of Helsinki. *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects,* adopted by the 18th World Medical Association (WMA) General Assembly, Helsinki, Finland, June 1964; amended most recently by the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000.

[12] Art II.6 governs therapeutic research, stating, "*The doctor can combine medical research with procedural care ... only to the extent that .... Research is justified by its potential ... therapeutic value for*

The doctrine was first introduced in the United States of America, by Justice Benjamin Cardozo in the landmark case of *Schloendorff v. Society of New York Hospital*[13] where he said that:

> "*every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable for damages*".

Looking at the above interpretation, it is clear that a surgeon could be liable for damages the moment he performed any procedure without any consent being obtained from the competent patient. Justice Benjamin was restating the ancient common law principle about unauthorized touching constituting trespass. Thus, the doctrine expands the liability of the medical profession and awarded more victims of medical negligence.[14] The above dictum was applied in the case of *Salgo v Leland Stanford Jr University Board of Trustees*[15] where the patient claimed that the doctor did not inform the risk of paralysis inherent in the treatment.[16] The case was the baseline for the physician to ensure that the patient clearly understands everything the procedure entails.

The task for the courts in the United States, in developing the doctrine, was to justify the creation of a duty in negligence to disclose information, in addition to the duty to take

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[13] (1914) 105 NE 92.

[14] Meisel D., (1977) "The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability by Way of Informed Consent," 56 *Nebraska Law Review,* 51, at p.77.

[15] 317 P. 2d 1093 (1960).

[16] *Natanson v Kline* 186 Kan. 393, 350 P. 2D 1093 (1960) followed the interpretation in *Salgo v Leland Stanford Jr University Board of Trustees* 317 P. 2d 1093 (1960).

reasonable care in treatment. It was assumed that the standard of care was, set by the medical profession. This method was described as a fiduciary relationship between a doctor and patient, casting on the doctor a fiduciary duty to disclose and any failure to this amounted to negligence.[17] The principle of fiduciary relationship has not been endorsed in many other jurisdictions in relation to medical negligence. [18]

Thus, it would seem that the American jurisprudence seems to have been more overtly concerned with patient choice. It was not until 1972, that the objective test of the 'reasonable patient test' was developed in *Canterbury v Spence*[19] where the doctor is to disclose all material risks involved, which is inherent to the proposed treatment in a given case. After *Canterbury* this test has become the majority standard applied by the courts.

1.2.1. Scope of a doctor's duty

The categories of a patient is never closed. At common law the duty of care owed by a doctor arises out of his relationship with his patient. This non-delegable duty may be owed both to a competent or incompetent adult, minors and third parties. The level of trust in any relationship depends on respect between the parties, and whereas the patient routinely respects at least the technical skills of the physician, respect, must also be shown by the doctor to the patient. Since the physician or doctor is the most competent

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[17] Kennedy, I. (1984) "The Patient of The Clapham Omnibus." *The Modern Law Review*, p.459

[18] For example in the United Kingdom the Bolam principle has been endorsed. *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582. Browne-Wilkinson LJ at p. 15 in *Sidaway v Governors of Bethlem Royal Hospital* [1985] AC 871, regarded fiduciary obligations as limited dealings with the property of clients or patients and refused to extend it further.

person, he or she has a duty to disclose sufficient information for the competent patient to understand the nature of the proposed treatment unless in cases of therapeutic privilege or emergency cases.

A doctor or physician's duty is all about diagnosis, prescribing treatment and advising their patients. Since communication is the essential tool of the medical fraternity towards a proposed treatment, the concern here is with regards to the basis of the legal duty to provide information in a doctor-patient relationship. In other words, what the doctor must do *prior* to acting, so as to ensure proper consent has been obtained for those acts. The common law courts have described the legal duty of a doctor, as a 'single comprehensive duty'[20].

A patient must understand or appreciate the implications or consequences of the consent. It is a competent patient's right and not the doctor's right to determine whether or not to undergo the proposed treatment. Inevitably, within negligence analysis, when patients have identified the particular risk of which they were not informed, which, they claim would have affected their decision, the question of reasonableness must be addressed.[21]

The word treatment is very wide. It could range from a surgery to any other forms of proposed treatment or therapy. Thus, the scope of duty also extends to the type of medication being prescribed to a patient and to warn them of any risk, which may be

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[20] *Reibl v Hughes* (1980) 114 DLR (3d) 1 (SCC).

[21] McLean, S.A.M. (1989), *"A Patient's Right To Know, Information disclosure and 'informed consent"* Aldershot: Dartmouth Publishing Company. p.94.

related to the taking of that medication, like side effects. This is because no drug is entirely safe, and risks also attach to many diagnostic results. The patient may have only consented to the taking of the medication prescribed but may not have consented to the other risks involved which he is unaware of.

Doctors in Malaysia are familiar with the doctrine and practice of informed consent[22]. Malaysia follows the common law principles of negligence and it is the duty of the doctor to disclose the material risk to the patient.[23] The purpose of an informed consent to preserve the right of a decision-making process, has been enshrined in our Section 11 of the Ethical Code of the Malaysian Medical Association,[24] which talks about consent for medical examination and treatment must be based on good communication between a doctor and patient[25]. This depends on the adequate information being provided by the doctor, which, enable them to understand.[26] No consent is valid if it is obtained:

i) by coercion or threat of force;

ii) when the party giving the consent is not aware of the full implications of consent.

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[22] Norchaya Talib (2007), "*Foo Fio Na v Dr Soo Fook Mun & Anor – Beneath (and Alongside) the Surface of Change,*" LR. p. 604.

[23] *Inderjeet Singh a/l Piara Singh v Mazlan bin Tasman* &Ors [1995] 2 MLJ 646.

[24] Code of Medical Ethics: *s. 1 Good Medical Practice*; p.5. "Malaysia is a multiracial, multireligious and culturally diverse nation with "belief in God" being the first tenet of the country guiding principles (Rukunegara). There are many core values running through the ethical beliefs of the various communities in Malaysia, which are worthy of emulation. Some of these values are extracted here for the guidance of our doctors."

[25] Ibid. The Code of the Malaysian Medical Association sets guidelines for the proper conduct of the doctor practicing in Malaysia. The Code is not, and cannot be, exhaustive. p. 7.

[26] Clause 3.3.1 of the Malaysian Code of Professional Conduct 1987, clause 3.3.1 emphasizes on respect

The Federal Constitution of Malaysia does not formally guarantee the right to health. The federal and state government share legislative powers over public health. The standard applied to the medical profession in this country falls to be judged upon the principles laid down almost two centuries ago in Great Britain[27]. However, it was not until 2007 that the courts, in the case of *Foo Fio Na v Dr Soo Fook Mun & Anor*[28] adopted the approach of the reasonable prudent patient test which was set out in *Rogers v Whitaker*[29] in Australia. Thus, reliance is no longer one hundred percent on the doctor. There is a need for members of the medical profession to stand up to the wrong doings, if any.[30]

The transatlantic doctrine of informed consent is not part of English common law, as doctors' disclosure was traditionally judged by references to the *Bolam*[31] test. The courts would ask what a reasonable doctor would have disclosed in the circumstances based on the commonly accepted practices of the profession. This law was however, given endorsement by the House of Lords on the understanding of the role and significance of the doctrine in three cases; firstly, in the case of *Sidaway v Governors of Bethlem Royal Hospital*[32] where the court regarded the fiduciary obligations propounded in the United States as being limited to dealings with the property of clients or patients, secondly in

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[27] Gopal Sr Ram, Judge, Court of Appeal of Malaysia, *The Standard of Care: Is The Bolam Principle Still The Law?"* [2000] 3 MLJ, lxxxi.

[28] [2007] 1 MLJ 593.

[29] [1992] 175 CLR 479.

[30] Siti Norma Yaakob FCJ in *Foo Fio Na v Dr Soo Fook Mun & Anor* [2007] 1 MLJ 593, p.611.

[31] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

Re F (a mental patient: sterilization)[33] and lastly in *Airedale NHS Trust v Bland*[34]. The courts attempt to restrict the scope of this doctrine, principally by means of the requirement of causation, the use of expert evidence as to the accepted medical practice and emphasis on the 'best interest of the patient' principle.[35]

This paradigm of self-determination is the process of knowledgeable and expressed choice whereby a mentally competent individual, who has been apprised of the risk and benefit of a proposed treatment, grants explicit permission for or rejects a particular intervention. It guides the process of medical decision-making by defining the parameters of the patient-physician dialogue. For example, a patient's free choice to refuse a blood transfusion. However, this doctrine has not been universally adopted in some countries[36].

While communication across cultures is indeed challenging it is not impossible. This includes any alternative treatment that may be available to the particular inherent risk in question. The components of this doctrine include:

a) disclosure of information by a physician or doctor to the patient

b) it is given by a competent patient;

c) it is given voluntarily and

d) it is an adequate informed consent

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[33] [1990] 2 AC 1.

[34] [1993] 1 All ER 821.

[35] ... 3rd ed. 2000, Butterworths, p. 582.

The problem arises when this may be overlooked at times. For example a patient suffering from colon cancer would need to know not only what the treatment may do to him or her and its attendant risk, but also other forms of treatment that exist, such as chemotherapy, or radiation therapy.

After half-century's effort to define and realize the concept of informed consent, it is still evident that historical, structural and practical obstacles remain. The extent of this duty has been questioned in many countries and different jurisdictions have had different outcomes, which, will be considered. Disclosing a diagnosis, especially in fatal illness like cancer is not a norm in some of countries, like South Africa and France.[37] Thus, with the doctor's duties, the patient's knowledge and the standards adopted, it appears that the relationship between a doctor and a patient is not always equally balanced.

1.3 Problem Statement

Age brings inevitable problems to our health, which may require relief to pain or treatment for chronic conditions. Though informed consent can be said to be the corner stone of medical practice in many countries, there still remains some complexity and uncertainties in the law with regards balancing the rights of the patient and the doctor. The patient expects the law to give him dignity, respect, independence, autonomy,

[37] Singapore Medical Journal 2007; 48(6): 560

information and self-determination.[38] Informed process involves a process of communication, which is currently one of the major problems faced globally in the medical fraternity.

The author believes that every surgery however, minor, carries a risk, which means, from the time a patient is wheeled into the operating theatre up the time the operation is over, which may be a success or failure. Besides that, authorities decided by the courts serve merely as guidance, which may or may not be applicable in other similar cases due to difference of opinion. As Professor Ronald Dworkin remarked that judicial decisions are political decisions at least in the broad sense that attracts the doctrine of political responsibility.[39]

However, the extent of the communication process between a doctor and his patient seems to remain unsolved in many cases, which might lead to a litigation process. The imperfect communication has limited the achievement of this doctrine. The fear is that doctors may resort to defensive medicine to protect themselves, which includes unnecessary steps and investigations carried out before the actual treatment. As Dunn L.J. said in *Sidaway v Governors of Bethlem Royal Hospital*[40], the doctors may inevitably be

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[38] Dr. Puteri Nemei Jahn Kassim, Mohamad Akram Shair Mohammad, "*Issues In Medical Law and Ethics: The Doctrine of Informed Consent in the United States, England, Australia and Malaysia: A Comparative Case Analysis*" Medical Law and Ethics Unit Law Centre, Ahmad Ibrahim Kulliyah of Laws, International Islamic University Malaysia, p.1.

[39] Barron, Collins, Jackson, Lacey, Reiner, Ross, Teubner. *Jurisprudence and Legal Theory, Commentary and Materials*. P 367 "Law and Adjudication: Dworkin's Critique of Positivism."(Available at yahoo.pdf.

concerned to safeguard themselves against claims, rather than to concentrate on their primary duty of treating their patients.

Unfortunately, patient preference is not always respected. People generally see things differently. This is problematic, because health professionals' attitude toward the value of particular treatments may differ from those of their patients.

Therefore, there are interpretational problems in the use of the word 'informed', which makes it less satisfactory in practice. The author believes that good medical ethics is achieved through shared decision-making, which offers benefit to both parties in negotiating treatment decisions. The doctrine involves a very important process and that process is known as communication. Doctors always have a strong hold on patients when the patient consents to the medical treatment. Though it is now a well established theory, it may not always be established in practice. It may result the distortion of the principle of causation in the medical duty to inform.

1.4 The rationale of the research

This research is important as the area of informed consent has a direct economic and sociological implication.

a. Economic implication

Society is paying a greater price to recover in order to lead a normal life. Malaysia's health policies are formulated as part of the federal government's five-year development plans and its annual budget.[41] It appears there is a need for a higher degree of understanding of the patient's actual needs and satisfactions to ensure the services they are paying for the medical treatment is not of waste. This includes the signing of a consent form in cases where surgeries are performed.

b. Sociological implication

Since the rationale is to enable a patient to make an informed choice, there are events where patients lack the technical skills to understand the medical aspects or may not be aware[42] of their right to the disclosure process even though some form of information may have been disclosed. Sometimes patients cannot understand highly technical information, which may make its provision meaningless and time consuming. This means communication may seem paradoxically to have become more difficult and yet more significant.

[41] For example in the Eight Malaysian Plan, it was said that primary health care will remain the focus of

1.5 The scope and objective of research

This study examines the sociological and legal factors underlying the doctrine in law and practice. Based on the above disparities, the author wishes to examine the doctrine of informed consent from two perspective:

Firstly, this study examines whether a good rapport in a doctor-patient relationship has been achieved in practice, which depends on the amount of information given by a doctor to satisfy the patient's needs under the principle of individual autonomy. The author also acknowledges the concept of patient-centred care, which is relatively new but in recent years has gained much support from policymakers, patients and health professionals. In other words, how well informed are we today.

Secondly, it also considers the extent to which a competence patient has understood the inherent risk involved to the proposed treatment before giving any consent. Access to accurate, relevant and understandable information is an essential prerequisite of informed choice. This means that the patient's participation is very important in decision-making.

1.6 Objectives

This project paper seeks to examine three fundamental issues:

(1) To examine the effectiveness of the doctrine of informed consent in practice by considering if there is good communication between a doctor and his/her patient in practice. It is largely derived from court decisions and comparison will be made with different jurisdictions.

(2) To evaluate how a patient's permission is sought in order to carry out a treatment since in practice this may not be totally effective.

(3) To investigate the attitudes of medical practitioners and patients by conducting empirical research.

1.7 Contribution of the research

In light of the above, the author hopes to provide the findings to the above objectives as to whether there exists a gap between the law and practice.

1.8 Methodology

The methodology for studying informed consent presents certain challenges. The author divided the research methodology into two main aspects, secondary and primary resources. Secondary resources include library research at the University Malaya Law Library, literature review, textbooks, journals, newspaper articles, law reports of various jurisdictions. Articles were also acquired through search engine such as JSTOR and Yahoo.pdf files.

This paper also presents the findings of an empirical research project to investigate perceptions of the consent process. In other words, the research is also based on primary findings[43] through qualitative and quantitative methods. There are various ways of collecting data in qualitative research. The methods used in this paper are by conducting structured interviews. The qualitative interview method allows the author to explore how patients understand the workings of the medical paternalism in a clinical setting that is, consent. There is also a highlight what is important to the patient in practice as opposed to relying on what the law is telling us.

Quantitative research allows positive approach to ascertain a systematic knowledge tabulation of specific data. These are analysed thorough statistical correlation with careful phrasing of evaluation questions. The preparation of the questionnaire is the central importance in survey research, with pre-determined set of questions designed to interview

[43] Thorpe, R and Lowe, A. (1991) *Management Research: an Introduction,* London,

doctors, nurses and patients in order to demonstrate the effectiveness of the doctrine in practice. The questionnaires would involve sampling of individuals though their responses to their questions. The interviews were restricted to doctors and patients. The results gathered from the interviews is to be assessed and analysed by the author to reflect accurately the application and understanding of this doctrine in practice.

1.9 Limitations

In preparation of this project paper, there were certain foreseeable constraints with regards to the outcomes of the findings. Firstly, there was the waiting for approval from the Ethics Committee of the hospital to conduct the interviews. Another was with regards to the difficulty of getting to make appointments to meet with the doctors. Some were not available due to time constraint and heavy schedule. Similarly there were patients who were reluctant to participate due to personal and confidential nature of the information required. However, every effort is used to minimize or where possible, eliminate these factors from affecting the results of this paper.

1.10.1 Background

1.10.1 Ethical concept

Informed consent is an ethical concept, which is an integral part of the medical ethics and medical practice. It is a state of mind of the patient.[44] We should respect each person's autonomy. It has been defined by the Oxford Dictionary as express willingness or give permission, it is applied in law as one of the essential duties on the part of a doctor which would otherwise amount to trespass to person, that is, battery[45] since consent is a state of mind personal to the victim[46]. In *Salgo v Leland Stanford Jr University Board of Trustees* [47]the first real attempt was made to outline the scope of the doctrine[48] of informed consent, where the court said:

"*A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.*"

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[44] Simon Deakin, Angus Johnston and Basil Markesinis. "Markesinis and Deakin's Tort Law, *Problems of Medical Law*". (5th Ed) pp292-293. Clarendon Press, Oxford

[45] The doctrine was fully recognized in 1957 in the American case of *Salgo v Leland Stanford Jr University Board of Trustees* 317 P. 2d 1093 (1960) where it acknowledged that the patient needs adequate information about the nature of the proposed treatment, its risk and alternatives in order to make a decision.

[46] per Lord Diplock in *Sidaway v Bethlem Royal Hospital* [1985] A.C. 871, 894. It was held by the House of Lords that a doctor owed a legal duty to his patient to inform him of all material risks in the course of a treatment. Failing which the doctor would have been guilty of a breach of his duty of care to the patient.

[47] 317 P. 2d 1093 (1960).

[48] McLean, S.A.M. (1989), "*A Patient's Right To Know, Information disclosure and 'informed consent"* Aldershot: Dartmouth Publishing Company, p. 86.

What must be of great concern to a doctor is that the complaint by a patient need not be to the particular procedure that was used without proper care and skill but rather that it was carried out without proper permission of the patient. The level of disclosure requires moral weight to be attached to patient autonomy or self-determination and the level of moral responsibility for this is placed on the shoulders of the doctor.

Today, an adult patient does not accept whatever treatment the doctor thinks best due to a better understanding. Patient autonomy is important to all major theories of medical ethics because it is considered to be needed or implied by the patient's rights (rights-based theories), the patient's bests interests (for duty-based theories)[49], the maximization of preferences or interests (for utilitarian theories) and human flourishing. Even a minor nature of medical treatment should not proceed unless consent is obtained. The ethical principles of beneficence, autonomy, non-maleficence and justice must be considered.

1.10.2 Principle of Autonomy and Paternalism

The rationale behind this doctrine is to promote individual autonomy, which means the ability to think, decide and act freely and independently.[50] Thus, if information disclosure is to protect patient autonomy, then obviously all relevant information or risk should be disclosed.[51] This is when the word 'informed' used is to imply that information has been given and received.

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[49] See Chapter 2, p.28.

[50] Keown, J., (1995) "To Treat or Not to Treat: Autonomy, Beneficience and the Sanctity of Life?" 16

Ethically, there is a need for a standard that balances beneficence and respect of patient's autonomy. It is said that a patient's autonomy is a well-known principle in theory, but little can be said in practice. This principle also claims heritage from religion, natural laws and moral philosophy. In determining this, it is essential to define the scope of legal requirement of an informed consent.[52]

In practice autonomy may be constrained by beneficence, where a patient may make an autonomous choice only to a limited extent or does not make a decision at all. This will relate to the question of whether the consent was obtained on the patient's free will.

As Professor Ronald Dworkin explains:

> "*...Recognising an individual right of autonomy makes self-creation possible. It allows each of us to be responsible for shaping our lives according to our own coherent or incoherent – but, in any case, distinctive – personality. It allows us to lead our lives rather than be led along them so that each of us can be, to the extent a scheme of rights can make this possible, what we have made of ourselves...*"[53]

Paternalism on the other hand is where the doctor's knowledge and his ethical obligation to do good, that is, what is best for the patient. Patients have certain expectations of the outcome of the treatment and find it hard to accept mistakes by doctors as a noble figure.

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[52] Supra, n.44.

[53] Dworkin, Ronald, M. 1993 "*Life's Dominion: An Argument about Abortion, Euthanasia and Individual*

Therapeutic privilege is inherently paternalistic which is considered as another ethical issues.

Being health consumers, patients now expect answers to their questions but the element of trust can still be indispensable in some cases. This confirms the position that the doctrine of informed consent has shifted the practice of paternalism to the individual autonomy whereby patients should be given sufficient information and be allowed an independent decision-making about their health.

1.10.3 The Standards of Disclosure

Basically three standard models of informed consent are evident, namely the reasonable physician standard, the reasonable patient standard[54] and the subjective standard which applies to what the patient needs to know and understand in order to make an informed consent.[55] According to J Kennedy and A. Grubb[56] there are three options in setting such legal standards[57]:

i) A doctor should be under a duty to pass on all information, which the patient wishes to know. This is the *subjective test*[58] and is rights-based philosophy.

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[54] In *Salgo v Leland Stanford Jr University Board of Trustees* 317 P. 2d 1093 (1960) it gave rise to two competing judicial standards, namely the physician based standard and the reasonable patient standard.

[55] Yousuf R M, Fauzi A R M, How S H, Rasool A G, Rehana K, "Awareness, knowledge and attitude towards informed consent among doctors in two different cultures in Asia: a cross-sectional comparative study in Malaysia and Kashmir, India," *Singapore Med J* 2007; 48(6): 559, p.2.

[56] I. Kennedy & A. Grubb (eds) "*Principles of Medical Law (1998).*

[57] I. Kennedy & A. Grubb, "*Medical Law*" Butterworths, 2000, p.679.

ii) A doctor should only pass that information which any reasonable patient would wish to know. The weakness of this is that it is a compromise as it takes into account the patient's right to be informed but at the cost of converting the actual patient into a hypothetical reasonable patient.

iii) Doctor's duty should be to inform the patient of that which doctors as a profession think it appropriate for the patient to know. This is philosophy of paternalism where the doctor is the better judge of what to inform.

Generally, the law requires disclosure only of "*material risk*"[59] rather than general risk. Material risk includes the patient's concern which is a subjective patient test; foreseeable risks which is an inherent risk the doctor must disclose and is a clinical judgment; and lastly, what a reasonable man would consider to be significant. This is the reasonable prudent patient test. The test is based on the ethical principle of autonomy.

What is important is that the physician's practice in disclosing should not vary, as this may cast substantial doubt whether majority prudent patient provide similar amount of information. Doctors themselves may differ on diagnosis and appropriate therapy. With one doctor the patient becomes a friend but it is hard to establish such a relationship with several doctors sporadically[60]. This is so when a patient in hospital care is treated by a number of doctors. In this case the patient does not feel he has his own doctor, the incidence of complaints arise.

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[59] Emphasis added.

[60] Omnibus," *The Modern Law Review*, p.467.

As stated in the case of *Hunter v Hanley*[61] '[i]n the realm of diagnosis and treatment there is ample scope for genuine difference of opinion.' Having said so the impediments of standards do not justify a shortfall of effort towards the application of this doctrine.

1.10.4 Theories of duty on disclosure

A duty to disclose is not absolute even though it is needed for patient to make decisions. However, duty to disclose can become an ethical duty to disclose, when it is detriment to the patient. Most major theories will impose a duty, which is absolute on doctors to disclose information in detail because of the therapeutic privilege exception, which allows retention of some information rights to be balanced against any competing rights of others. Utilitarian theories[62] will recognize the utility-maximising consequences of full and frank disclosure but will recognize the potential negative consequences of doctors and patients devoting proportionate attention to risks, which is small.

With such uncertainty in the system, it would be important to look outside the jurisdiction of Malaysia with regards to the law and practices, which has been adopted and bearing in mind if any of the three options propounded in *Re C (an adult: refusal of medical treatment)* [63] have been adopted.

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[61] 1955 SC 200, at p.217.

[62] *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118.

CHAPTER 2

THE PRACTICE OF DISCLOSURE IN A DOCTOR-PATIENT RELATIONSHIP

2.1 Introduction

This chapter will consider the first objective with regards to the practice of the doctor's duty to disclose information. It will also make reference to the practices adopted by other countries by looking at case reviews. This chapter will also address the issue of whether there is good communication between a doctor and the patient in practice and the difficulties being faced by doctors. By doing this, the author proposes to consider the first important component of the doctrine of informed consent, namely disclosure of information[62].

2.2 Disclosure of information to a patient

In Malaysia, the judicial system largely followed the English law common law principles closely[63]. A duty to disclose such information is different from a duty to diagnose and treat. It must fully elaborate the other components of informed consent, namely comprehension and voluntary choice.[64] The duty to treat is in accordance with the doctor's skill, whereas in the duty to diagnose, there are certain factors that must be taken

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[62] See Chapter 1, p.9.

[63] *Chelliah a/l Manickam & Anor v Kerajaan Malaysia* [1997] 2 AMR 1856; *Kamalan a/p Raman & Ors v Eastern Plantation Agency (Johore) Sdn. Bhd.* [1996] 4 MLJ 674; *Elizabeth Choo v Government of Malaysia* [1968] 2 MLJ 271; *Chin Keow v Government of Malaysia* [1967] 2 MLJ 45.

into account. Surgeons are by their very nature confident individuals, which is a necessary component allowing the patient to see no uncertainty in his doctor. In order to disclose information the professional standard is the most paternalistic, while the particular patient test is the most patient-centred.

Besides that the obligation to provide adequate information implies an obligation for the physician or doctor to be current in their own knowledge.[65] Judging from this it can be said that the doctor is faced with a rather complex task in practice.

If a surgery is to be carried out, then the patient must be told what and why it is being done. The manner in which disclosure should be made is one calling for skill and sensitivity. It should not be a case where the patient is presented with an indigestible lump for information. Sometimes, it may take more than one session. This is because depending on the type of treatment, which is involved the patient might need to comprehend and retain the necessary information[66].

However, all surgery under general anaesthetic entails some risk. Such risks are ordinarily known to the patient. Examples of material risk include the nature of the procedure itself or even, the risks of partial paralysis. Besides that risk may also be inherent in the procedure in cases of patient who has a heart problem, or lung condition which may aggravate the risks even further, no matter how minimal. Thus, the relevant

question to ask is what care would their patients prefer if they had all the facts, as some might prefer taking drugs to avoid surgery. Some people may even opt for traditional remedies rather than undergoing a surgery. So at the end of the day, no matter what decision the patient makes, it is important that the doctor has discharged his duty accordingly.

Apart from that, the question of capacity, that is, understanding the details of the complex medical procedure and any risk involved, which is inherent to the treatment, must be taken into account, as it could impact on the effectiveness of this doctrine. Accordingly, there are two factors that need to be considered as to whether a doctor has disclosed the necessary information in the proposed treatment to the patient. Firstly, when and how much the doctor is to inform the patient about the inherent risks; and secondly, in the event of failure, the standard to be applied.

2.3 Information that a doctor should convey to a patient

Sometimes, doctors may be faced with certain difficulties in deciding whether the kind of communication to the patient is necessary for informed consent. This is particularly so in a clinical context, or where there is underdeveloped professional communication skills, or even language barriers between technical jargons and ordinary comprehension. Thus, in order to decide which standard would be practical, it would be useful to adopt the views

proposed by J Kennedy and A. Grubb[67]. Their view is that firstly, a doctor should be under a duty to pass on all information in cases where the patient wishes to know; secondly, a doctor should only pass that information which any reasonable patient would wish to know and thirdly, the doctor's duty may be based on the philosophy of paternalism where the doctor is the better judge of what to inform.

As far as information and advise is concerned it is the patient's right to decide whether or not to go through the procedure having taken into account the possible risks and potential benefits. For instance, a woman with breast cancer is entitled to know not only what radical mastectomy may do to her and its attendant risks but also other forms of treatment that may exist, such as chemotherapy, radiation therapy. Otherwise she is not sufficiently informed. In practice, the duty of doctors to disclose the risks to the patient has been accepted by the judiciary in Malaysia in the case of *Liew Sin Kiong v Dr Sharon DM Paulraj.*[68] The duty is measurable according to the standard set up by the opinion of a responsible group of doctors.

2.2.1 The position in the United States

For many years the attitude of the courts in the United States were of the view that what a doctor should disclose to his patient in relation to the inherent risks of proposed treatment, would depend on what a reasonable doctor would have done in similar

[67] I. Kennedy & A. Grubb, *"Medical Law"* Butterworths, 2000, p.679. There are three options in setting ... Chapter 1, pp. 21-22.

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circumstances. This was until its landmark case of *Canterbury v Spence*[69] where the 'reasonable patient test'[70] was formulated and at 784, Robinson J said that[71],

> *"respect for the patient's right of self determination on a particular therapy demands a standard set by law for a physician rather than one which physicians may or may not impose upon themselves."*[72]

It is an objective test in the sense that it is not whether the patient himself would have attached significance to the risk, but rather whether a reasonable person in the patient's position would have done so. The court therefore defined a standard that revolved around the needs of the patient and required disclosures when a reasonable person, in what the physician knows to be the patient's position, would be likely to attach significance to the risk in deciding whether or not to undergo the therapy.

The court enunciated four propositions[73] in this case:

i) the root premise is the concept that every human being of adult years and of sound mind has a right to determine what shall be done to his body,

ii) the consent is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant on each,

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[69] 464 F. 2d 772 (D.C. Cir. 1972). The physician was under a duty to disclose all 'material risk' inherent in the proposed treatment. Prior to this case, whether a risk is material or not would be viewed according to medical opinion. The significance of this case is that the test of 'materiality' would now rest with the reasonable prudent patient's point of view.

[70] This opinion was favoured by Lord Scarman in *Sidaway v Bethlem Royal Hospital*[1985] A.C. 871.

[71] In Canada, *Reibl v Hughes* (1980) 114 DLR (3d) 1 expressed approval of the doctrine of informed consent in *Canterbury v Spence* 464 F. 2d 772 (D.C. Cir. 1972).

[redacted] 3rd ed. 2000, Butterworths, pp. 682-683.

iii) the doctors must, therefore, disclose all 'material risks'; what risks are material is determined by the 'prudent patient' test formulated by the court,

iv) The doctor, however, has what the doctor called a 'therapeutic privilege', which is an exception where the doctor may withhold information from his patient where it would cause the patient not to be able to make a rational decision as being too distraught.

Lastly a written consent is deemed to be ineffective if the patient failed to understand material information about the procedures to be performed. This will be considered in detail in the next chapter.

Recently, the American Medical Association[74] website contains information and guidelines regarding informed consent advising what practicing physicians should go over with their patient. This includes:

i) the patient's diagnosis, if known;

ii) the nature and purpose of a proposed treatment or procedure;

iii) the risks and benefits of a proposed treatment or procedure;

iv) alternatives;

v) the risk and benefits of the alternative treatment or procedure; and

vi) the risks and benefits of not receiving or undergoing a treatment or procedure.

[74]American Medical Association, Informed Consent. (Available at http://www.ama-assn.org/ama/pub/category/4608.html. Last downloaded on 28 October 2008).

In return the patient is able to ask questions to elicit a better understanding of the treatment or procedure, so as to enable him or her to make an informed decision. Increasingly in the United States, the practice of informed consent has become extremely legalistic, focused on preventing lawsuits against institutions rather than protecting individuals in therapy.

2.2.2 The position in the United Kingdom

In English law, patients are not entitled to the fullest possible information about the treatment they receive. There is no doctrine of 'informed consent' as such. The principle of medical paternalism has a stronger hold compared to the principle of patient autonomy. This is where a patient is so fragile that full disclosure would overwhelm them at that time which would be detrimental to the patient's health.[75] The general duty of a doctor to a patient was interpreted as extending not only to acts but also omission in this case the failure to inform properly. Clearly, this arises whenever the doctor proposes a *therapeutic intervention*[76] and a doctor is not liable if he has acted in accordance with a practice accepted.

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[75] For example where a road accident victim is in a critical condition asks about family members or where a patient asks about the extent of burns or internal injuries at a critical time. Therapeutic privilege can only be consistent with maximal autonomy where a patient is in good faith deemed incompetent or a good faith attempt is being made to assess a patient's competence.

[76] Emphasis added.

Over the year, England has been very comfortable with the '*Bolam*[77] principle' or the reasonable prudent doctor test. The test is whether the doctor acted reasonably in the amount of information given. In this case Mr.Bolam was not informed of the risk of fractures because the doctor said that it was a matter of medical judgment. This means that although the patient should receive information about the proposed treatment, the kind of information imparted would rest in the hands of the doctors involved. The principle was subsequently applied in *Hills v Potter*[78] where paralysis resulted from an operation to correct a neck deformity. It was alleged that the surgeons had never informed the patient of the risks but the court held that the standard of disclosure is to be based again on the medical judgment that is, being a professional standard.

It was a year later that the scope of the doctor's duty and the doctrine was finally considered in detail by the House of Lords in the case of *Sidaway v Bethlem Royal Hospital*[79] but majority of the judges were of the opinion, which was against informed consent. It was argued with *obiter* statement that the doctor should use his discretion in not disclosing to the patient of a risk, which might harm the patient. This is the position considered in a case of whether a doctor should be open and direct with a patient who is dying of cancer. The doctor should not volunteer information to a patient unless asked

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[77] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582

[78] [1984] 1 WLR 641.

[79] [1985] A.C. 871. The patient's spinal cord was damaged leaving her disabled. The neurosurgeon had told her about the damage to the nerve root (2% risk) but had not told her of the damage to the spinal cord (1% risk). House of Lords held that it is for the doctor to decide what information to disclose to the patient.

for. Only Lord Scarman who dissented[80] and favours the 'prudent patient' test for medical evidence, as the court may assess the degree of probability and the seriousness of possible injury.

In conclusion his Lordship said that:

> "*...English law must recognize a duty of the doctor to warn his patient of risk inherent in the treatment which he is proposing: and especially so, if the treatment be surgery. The critical limitation is that the duty is confined to material risk. The test of materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person in the patient's position would be likely to attach significance to the risk. Even if the risk be material, the doctor will not be liable upon a reasonable assessment of his patient's condition he takes the view that a warning would be detrimental to his patient's health.*"[81]

In other words, medical evidence will be a significant factor in determining whether such a risk is material and whether withholding information was justified[82]. Other factors include, likelihood and gravity of the risk, the desire of the patient for information, the patient's mental and physical health, the need for treatment and alternatives available[83].

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[80] His Lordship was inclined in accepting the four propositions expounded in *Canterbury v Spence* 464 F. 2d 772 (D.C. Cir. 1972).

[81] Ibid. at pp. 889-890.

[82] Kennedy and Grubb *Medical Law*, 3rd ed. 2000, Butterworths, p. 690.

[83] Puteri Nemie bt Jahn Kassim (2007), "*The Reasonable Prudent Patient Test: A Visible Test for this Millenium?*" LR, p.608.

On the other hand a doctor may be liable if he intentionally applies a procedure to a competent patient who is not informed of the basic nature of that procedure. However, this is difficult in a situation where a doctor has failed to provide information before the treatment because the patient had voluntarily refused that information. Some have taken the view that the lack of minimal information will render the decision non-autonomous or at least not a valid consent or refusal. While, others are of the opinion that some disclosure, however minimal, is required irrespective of the views of the patient. The lack of information would render the decision uninformed and so any consent would be invalid.

The duty to disclose risk was stated in the dissenting judgment of Lord Scarman in *Sidaway.*[84] It has been developed further in 1997 in the case of *Bolitho v City and Hackney Health Authority*[85] where Browne-Wilkinson LJ in his judgment said that in vast majority of cases the fact that distinguished experts in the field are of a particular opinion will demonstrate the reasonableness of that opinion. The test is said to be a simple modification of the *Bolam*[86] test, which provides opportunity to a new approach.

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[84] *Sidaway v Bethlem Royal Hospital*[1985] A.C. 871.

[85] (1997) 3 WLR 1151. The use of the three adjectives, responsible, reasonable and respectable, had to be satisfied that the exponents of the body of opinion relied on can demonstrate that such opinion has a logical basis.

[86] *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118.

A further development was seen in the case of *Chester v Afshar*[87] which said there are two purposes that a doctor fulfils in warning his patients of risks: firstly, is to avoid occurrence of the particular risk of physical injury which the patient is not prepared to accept and secondly, to ensure due respect is given to the autonomy and dignity of the patient[88]. Here, the patient was unable to argue but-for the doctor's failure to warn her of the risk, she would have decided not to undergo the proposed surgery. This case can be said to have advanced English law.

Today, more and more doctors in the United Kingdom are endorsing disclosures of risks to patients in practice. Like the United States, there are guidance from the General Medical Council,[89] directing doctors to take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment[90]. In 2002, the Department of Heath in its *Reference Guide To Consent*[91] has issued detailed information to doctors to enable them to assess how much information to provide to their patient. However, in light of the decision in *Chester v Afshar* [92] these guidelines would definitely need updating.

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[87] [2002] 3 All ER 552. However, the case indicated that the traditional 'but-for' test may not always be appropriate and that the courts may introduce new and radical approach to causation.

[88] Id. 594.

[89] GMC, *Seeking Patient's Consent: The Ethical Considerations* (1999).

[90] *Medicine, Patients and The Law,* Margaret Brazier and Emma Cave (4th Ed), 2007, p 114.

[91] Vivienne Hapwood, *Modern Tort Law*, (Sixth Ed), p. 464.

[92] [2002] 3 All ER 552.

2.2.3 The position in Australia

The position is somewhat different in Australia where in many cases the standard of disclosure is based on medical judgment. As of late, the judiciary has scrutinized the medical practice. There has to be a nexus between non-disclosure of the risk on the part of the doctor and the damage suffered by the patient. The needs of the patients are crucial in determining the issue. In *F v R*[93] King CJ stated that the court has an obligation to scrutinize professional practices to ensure that they accord with the standard of reasonableness imposed by the law.

Causation has also been laid down as a requirement for medical negligence. As can be seen in the case of *Chappell v Hart*[94] the plaintiff alleged that the doctor had failed to warn her of the risk of damage to her vocal cords, making her lose the chance to defer the treatment. The court applied the aspect of causation and held that since the patient was a principle education officer whose vocation demanded a quality voice, a fact known to the doctor, there was a casual link between the failure to warn by the doctor and the damage suffered by the patient. Similarly, the English courts in the case of *Chester v Afshar*[95] the patient after removing her three inter-vertebral discs, suffered nerve damage resulting in paralysis, which was a small known risk. The court applied the chain of causation which

[93] (1983) 33 SASR 189, at p. 194.

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denotes the failure on the part of the doctor to warn her of the risk, which otherwise she would have avoided the operation.

In both cases, neither of the claimants could prove that she would have avoided the risk. The only material difference between them was that in *Chappell v Hart*[96] the claimant alleged that had she had been warned of the risk she would have sought a better surgeon, whereas in *Chester*[97] the claimant merely said that she would have deferred the surgery. However, both the claimants had no choice but eventually went precisely the same type of surgery, as there was no other remedy for them. Besides that, policy issues were important factors.

In 1992, the 'prudent patient test' and the 'prudent doctor test' was resolved in the case of *Rogers v Whitaker*[98] which had enormous influence on the development of medical jurisprudence of disclosure of risks in Australia. Both the cases of *Bolam*[99] and *Sidaway* were considered in this case. In his judgment Lord Woolf MR said that if there is a significant risk which would affect the judgment of a reasonable patient then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk if the information is needed so that the patient can determine for him or herself as to

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[96] [1998] 156 ALR 517.

[97] Supra, n 95.

[98] (1992) 175 CLR 479.

[99] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

what course he or she should adopt. According to Mason CJ, the scope[100] of the doctor's duty to disclose a material risk, include:

i) If in the circumstances of a particular case, a reasonable person in the patient's position, if warned of the risk would be likely to attach significance to it; or

ii) Subject to therapeutic privilege, if the medical practitioner is or should reasonably be aware that a particular patient, if warned of the risk, would be likely to attach significance to it.

The case was more patient-centred with greater recognition of patient self-determination than English law. It held that how much information[101] the doctor should impart, cannot be determined by "any profession or group in the community", but rather, it should be determined upon consideration of a number of complex factors such as the nature of the matter to be disclosed; the nature of the treatment; the desire of the patient for the information; the temperament and health of the patient and the surrounding circumstances. The opinions of medical experts should not be the main consideration but it is for the courts to decide the appropriate standard[102].

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[100] Supra, n. 98 at p. 490.

[101] ibid at p. 194.

[102] Considered by King CJ in *F v R* (1983) 33 SASR 189, at pp 192-193. This approach is similar to that subsequently taken by Lord Scarman in *Sidaway v Bethlem Royal Hospital* [1985] A.C. 871.

Initially, it was commonly understood *Rogers v Whitaker* [103] might only apply to cases where there was a question of negligent advice only but in 1999 the High Court made it clear in the case of *Naxakis v Western General Hospital and Another*[104] that it also applied to treatment.

2.2.4 The position in Malaysia

Doctor-patient communication or miscommunication has been the focus in several cases in Malaysia. These cases have shown that the issue has not been whether the information is adequately given to enable the patient to make an informed consent but rather, if any information about risks inherent in the proposed treatment was in fact given to the patient. Malaysia has closely followed the English common law position for many years in determining the extent of disclosure as stated in *Sidaway v Bethlem Royal Hospital*[105]. The principle of autonomy is limited to a patient as far as diagnosis and treatment is concerned as the doctor provides this according to their medical skills. Until 2006, the *Bolam* principle was widely used by the Malaysian courts. Some of these cases include the following:

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[103] (1992) 175 CLR 479.

[104] (1999) 162 ALR 540. Here the appellant brought an action against the senior neurosurgeon and the hospital for failure to properly diagnose and that the negligence of the surgeon led him to suffer serious and permanent physical and intellectual impairment.

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[105] [1985] A.C. 871.

Liew Sin Kiong v Dr Sharon DM Paulraj[106] where the patient failed to prove that the doctor had not acted in accordance with the practice the judge felt that the consent form did not state that the doctor had informed the patient of the risk of infection, it did not mean that the risk was not explained. The doctor was allowed the 'therapeutic privilege' in deciding whether or not to disclose the risk.

Payremalu Veerappan v Dr Amarjeet Kaur & Ors[107] was a case where the court upheld the Bolam approach and said that the doctor was not negligent in not informing the patient of the risk involved to the proposed treatment. It was also held that the negligence for non-disclosure must relate to a risk, which is real and not farfetched and fanciful.[108]

However, a departure from the *Bolam* principle was seen for the first time in Malaysia in *Kamalam a/p Raman & Ors v Eastern Plantation Agency (Johore) Sdn Bhd Ulu Tiram Estate, Ulu Tiram, Johore & Anor*[109] where *Rogers v Whitaker*[110] was fully endorsed.

Richard Talalla J[111] in that case held that the standard of care is no longer a medical judgment. This can be taken to apply equally to the doctor's duty to disclose the risks for which the reasonable patient test would apply rather than the peer judgment. Even Gopal

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[106] [1996] 2 AMR 19.

[107] [2001] 4 CLJ 380.

[108] Other cases include *Swamy v Matthews* [1968] 1 MLJ 138; *Chin Keow v Government of Malaysia & Another* [1967] 2 MLJ 45; *Elizabeth Choo v Government of Malaysia* [1970] 2 MLJ 171.

[109] [1996] 4 MLJ 674.

[110] (1992) 175 CLR 479.

[111] Ibid. p.686.

Sri Ram J said that despite the unequivocal rendition of the doctor's duty to satisfy the court about the observance of the standard of care as required by law, the court is sometimes understood to have drawn a dichotomy in approving *Bolam* in matters of diagnosis and treatment but departing from it in matters of advertisement and information.[112]

Rogers v Whitaker[113] was again applied in *Tan Ah Kau v Government of Malaysia*[114] where no consent was actually given by the patient, as the content of the consent form had not been fully and comprehensively explained to the patient. There was poor communication between the doctor and patient.

Similarly, in *Hong Chuan Lay v Dr Eddie Soo Fook Mun*[115] one of the issues involved the failure to inform the patient of the risk of paralysis.

This principle of informed consent only seeped into our law efficiently through the case of *Foo Fio Na v Dr Soo Fook Mun & Anor*[116]. This landmark case distinguished the facts

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[112] Judge, Court of Appeal of Malaysia, The Standard of Care: Is the *Bolam* Principle Still The Law? The Malayan Law Journal [2000] 3 MLJ. pp12-13

[113] (1992) 175 CLR 479.

[114] [1997] 2 AMR 1382. In this case, the servant of the defendant carried out the surgical operation on the plaintiff who had a history of an injury to his back caused by a piece of wood. An orthopedic surgeon examined the plaintiff and diagnosed spinal tumor. The cause of the tumor was ascertained after some tests as low grade astrocytoma and the plaintiff was paralysed waist down.

[115] [2001] 3 MLJ 725.

[116] [2007] 1 MLJ 593.

of the instant appeal from the facts in *Bolam*[117] and demonstrated the prudent patient test where the hospital was held liable. The well-known facts related to the medical treatment of the plaintiff following an accident in 1982. She claimed that she was unaware of the risk involved as the doctor did not explain the risks of the surgery despite having been asked. She was merely given the assurance that it was a minor surgery, which eventually led to her paralysis. According to Dato' Siti Norma Yaacob in her judgment:

> "... *in the realm of diagnosis, treatment and the duty to warn, the ruling of the High Court of Australia in Naxakis v Western General Hospital and Another (1999) HCA 221 was able to settle the ongoing doubt which existed in Rogers v Whitaker, as to whether Rogers was restricted to cases relating to negligent advise only.* "[118]

The Federal Court in its conclusions stated that *Rogers v Whitaker*[119] test would be more appropriate and a viable test of this millennium than in the *Bolam*[120] test. The above mentioned decision has been recently cited in the case of *Lechemanavasagar a/l S. Karuppiah v Dr Thomas Yau Pak Chenk & Anor*[121]where the plaintiff alleged that the defendant did not explain that the operation to remove a fish bone was risky. A more recent case applying *Foo Fio Na's* test was *Chien Tham Kong v Excellent Strategy Sdn Bhd & Ors*[122] where the plaintiff alleged negligence on the part of the doctors who failed

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[117] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

[118] Ibid, p 607.

[119] (1992) 175 CLR 479.

[120] Supra, n.117.

[121] [2008] 1 MLJ.

[122] [2009] 7 MLJ 261.

to take proper precaution to prevent injury and making the initial diagnosis of stroke without considering alternative diagnosis. However, the case was dismissed with costs as the plaintiff had failed to establish that the doctor did not exercise the standard of care in the diagnosis and treatment.

Lastly, in the case of *Dr Ismail Abdullah v Poh Hui Lin*[123] the plaintiff had commenced an action against the defendant for medical negligence in non-disclosure of the risk which resulted in the death of her 57 year-old mother. The mother who was deeply jaundiced and she was given immediate ultrasound, which revealed biliary obstruction due to a stone at the lower end of the bile channel from the liver and gall bladder into the small intestine. The endoscopy failed and an operation was performed to remove the stones. Subsequently, she died due to acute respiratory distress syndrome (ARDS). The court applied *Rogers v Whitaker.*[124] It held that the defendant had been negligent in not informing the plaintiff and the deceased of the material risk involved but the therapeutic privilege of the defendant outweighed the duty to warn her of any material risk which would result in her refusing the life saving operation due to her severe medical problems.

Looking at the cases, it affirms that the position today stresses the need of a medical practitioner to inform his patient, who is capable of understanding and appreciating such information of the risks involved in the proposed treatment. It can be seen as a step towards patient-based standard but the question still remains as to its viability in practice.

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[123] [2009] 7 CLJ 167.

[124] Supra. n. 119.

Should it be accepted without any doubt, only then it can be said that this goes to promote the patient's autonomy as was discussed earlier in Chapter 1.

2.3 Conclusion

Although in the jurisdictions discussed the interpretation of what amounts to sufficient disclosure and the standard required may differ, there still remains a consensus on the basic elements constituting valid consent. Communication continues to be an obstacle in doctor-patient relationship. Given that a doctor cannot guarantee perfect results, there is always some element of risks involved. As such it may seem unfair to leave the entire element of risk on the part of the doctor who administers treatment. The role of the patient is also important which will be discussed in Chapter 3.

The American courts advocate the prudent patient test in *Canterbury,* while the English courts still hold strong to the *Bolam* principle until recently, where doctors are placing importance on the degree of communication with patients. In Australia the courts have moved away from the rigid *Bolam* approach and consider the matters to be judged by the courts, that is, the 'reasonable patient test'. Though, things only took a turn in Malaysia in 2007, there is still a division between doctors and the courts on this issue. There is the question of defensive medicine being practiced as an alternative method for doctors to avoid medical negligence litigation.

CHAPTER 3

OBTAINING INFORMED CONSENT FROM A PATIENT – PROCESS AND CAPACITY

3.1 Introduction

This chapter explains and evaluates as to how a patient's permission is sought before treatment is carried out. The process of obtaining consent is explained and its effectiveness in practicing "informed consent" is assessed.

Consent is not a form of mere formality but is an important tool of individual right to have control over one's body. It is the patient who decides when treatment or surgery shall be carried out, where and when it will be done and by whom. Theoretically, this may look simple but in practice there seem to be some difficulties being faced by patients to decide.

Patients may be asked to sign consent forms before any operation but in reality, they may not understand what they are signing. This is due to the problem of doctor-patient communication.[125] Patient's comprehension of the disclosed information should be the major issue of judicial concern.

The first important thing to focus in this chapter is what amounts to a proper consent and secondly, who can consent, meaning whether a patient is competent or not.

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[125] *Tan Ah Kau v Government of Malaysia* [1997] 2 AMR 1382

3.2 Patient's understanding of informed consent

Although in the case of *Re C (an adult: refusal of medical treatment)*[126] discussed earlier the legal principles with regards as to how and when informed consent is to be obtained is laid down, an equally important question is whether adhering to the legal principles provides adequate protection to the patient. It also involves two other important elements, namely, comprehension and free consent. Comprehension requires awareness and understanding which is necessary for there to be freedom in consenting. This can be said to be the root to the medical problem.

Free consent is an intentional and voluntary act that authorizes the doctor or physician to treat. The efficacy and adequacy of free consent and comprehension will depend on the patient's decisions. In practice it is sometimes difficult to specify what consent consists of and requires. This is because informed consent includes freedom from external coercion and the author's concern is that whether any medical recommendations being made to a patient to improve his health is considered coercive or not. Pain is dehumanizing. The severer the pain, the more it overshadows the patient's ability to decide.[127] In other words, pain destroys autonomy. However, a woman who undergoes a screening of mammogram would encounter pain which is obviously not equivalent to consenting to something as invasive and painful.

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[126] [1994] 1 All ER 819 (Fam Div).

[127] Post, J. F., Blusteein, J. Gordon E., Dubler, N.N. "*Journal of Law, Medicine & Ethics*", *24*. 1996: 348-

There is a lot of information for patient to digest and qualify. In doing this, they may weigh these risks and benefits very differently depending on their age, lifestyle and personal values. The level of information suitable for some people is likely to be insufficient for many others. Besides that, patients value different types of risks and benefits quite differently.[128]

Acknowledging the limitation of disclosure of information, greater attention needs to be given to comprehension and decision-making. There is concern as to how much a patient understands and therefore consents to the procedure involved. This is because there has been some contentious issues in the United States for example for the storage of biological specimens gathered during research and their potential commercial use later. For example in the case of *Moore v Regents of the University of California*[129] a spleen from an individual was later used to develop a cell line that was highly profitable. The court decided that the patient had signed away his right to his biological specimens and their use when he signed the consent form.

The question of understanding may vary in practice in the sense it could be affected by the language used, the state of mind of the patient or may be the time of day when this information is imparted. Thus, there is a need for understanding and grasping the information. This begs a question as to whether the patient be denied the right to make a decision if he or she does not seem to understand all of the information, yet expresses a strong desire to undergo the treatment. This may not be simple as the author feels that

[128] *Canterbury v Spence* 464 F 2d 772 (1972), objective test of the 'reasonable patient test' was developed.

based on the standard of care, the higher the potential risks is involved, the higher is the threshold for comprehension, which is needed. Besides that Western values may clash with the Eastern, which may place greater emphasis on spirituality, family and community.

A doctor examining or even injecting a patient makes contact with the patient's body. Here, he commits no wrong unless the patient disagrees. Thus, consent is mandatory and it can be given expressly or impliedly. For example, consent can be implied when a doctor checks the pulse of a patient or even a dentist who examines the teeth of a patient. It is obvious that the person sitting in the dental chair is not going to tell the dentist that, "you may hereby place your object into my mouth and examine the condition of my teeth". Action obviously speaks louder than words. [130] It depends on the circumstances of the case.

Consent is not true if it obtained by fraud or misrepresentation of the nature of what is to be done.[131] In *R v Tabassum*[132] a bogus doctor who persuaded several women to allow him to examine their breasts, claiming he was conducting research into breast cancer, was convicted of assault. The women's consent depended on their belief that he had medical qualifications and that the consent to which they agreed had a proper medical purpose.

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[130] A person holds out an arm to be vaccinated.

[131] Lord Donaldson in *Sidaway v Bethlem Royal Hospital*[1985] A.C. 871

[132] [2000] Lloyd's Rep Med 404. CA

Regardless of the above, what matters at the end of the day is the 'reality' of the consent.[133] A patient's consent is only real if he or she has been adequately informed about the proposed procedure. The crucial question is what information does the patient have when agreeing to the treatment. As stated by Bristow J in *Chatterson v Gerson*[134]

> *"In my judgment once the patient is informed in broad terms of the nature of the procedure which is intended and gives his consent, that consent is real and the cause on which to base a claim for failure to go into risks and implications is negligence, not trespass."*

The issue is whether the lack of awareness of risks inherent in a medical procedure can affect the validity of the patient's consent. This boils down to the communication problem as can be seen in the case of *Tan Ah Kau v Government of Malaysia*[135]. The question is whether at the time of signing the consent form the plaintiff understood the nature and consequences of the consent and knew of the subject matter. On this issue the court held there was no consent, as the contents had not been fully and comprehensively explained to the plaintiff. This vitiates the reality of consent. The doctor's medical education has merely prepared him how to treat the patient, but not communication skills.

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[133] *Chatterson v Gerson* [1981] 1 QB 443

[134] [1981] 1 QB 443

In the United States it is said that informed consent in medical treatment may differ from that in reproductive and sexual health research because the participants are of a different group altogether, are usually healthy and have broader range of choices.[136]

Autonomy is not the only characteristic of persons that is the basis for dignity. Human beings cannot be adequately understood only in terms of self-determination because they are relational in structure of their personalities, their needs and their possibilities.[137] Informed consent in this sense is not an end, but a means, not only to the responsible participation by patient, but also is a mean to a new form of relationship between patient and physician/ doctor.

Besides that a consent once given may be withdrawn at any time while still competent to do so. In other words, if during a procedure a patient withdraws the consent to that procedure then the doctors must halt the process. But a different outcome was derived in the case of *Mitchell v McDonald*[138] where the patient who suffered from acute fracture muscular pain in her chest consented to receive cortisone injection directly into her chest muscle but it punctured a lung resulting a partial collapse. At the time of the procedure the patient cried out "For God's sake, stop". She argued that this constituted a withdrawal but the trial judge interpreted it as but a cry of pain. This may raise some form of uncertainty in this context with regards to the adherence to the doctrine in the strict sense.

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[136] Informed Consent: From Good Intentions to Sound Practices (at www.popcouncil.org. Last downloaded on 6 November, 2008)

[137] Informed Consent (at http://www.acog.org/from_home/publications/ethics/ethics009.pdf p.11. Last downloaded on 5 November 2008)

[138] (1987) 40 CCLT 266, 80 AR 16, 53 Alta LR (2d) 4b (QB)

The problem with patient autonomy and information disclosure is that the need to make rational decisions. In other words, though it is important that the patient requires information to make a rational decision, it is not clear that the making of the rational decision is the delimitation of his or her rights to autonomy or self-determination. For example choice is taken to prefer illness to therapy, when therapy is known to have a reasonable chance of success.

3.3 Who can give a valid consent

3.3.1 Competent patients

Competence is a pivotal concept[139] in decision-making about medical treatment. It is a state inherent in the individual patient, which cannot depend how much the doctor tells the patient. Therefore, competency is determined by reference to the unvarying conceptual standard or ability to understand. [140] A competent patient could range from the young to the old. The importance of capacity of who decides is also important.

Competence has been presumed as long as the patient modulates his or her behaviour, talks in a comprehensible way, remember what he or she is told and acts so as to appear to be a meaningful communication. This in turn creates a problem as to what constitutes adequate understanding, which is vague. For example, a person of full age and capacity

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[139] Grisso T. and Applebaum, P.S. *Assessing Competence to Consent to Treatment: A Guide to Physicians and Other Health Officials* (1998).

cannot be ordered to a blood test against his or her will as this is an infringement of their personal rights.

Thus, the mental and physical health of the patient is an important factor in determining the materiality of risks. This would include the patient's medical history, if any. In *Tiek Huat Tai v Saxon*[141] the court held the doctor liable for not informing the patient about the risk of the proposed treatment as the doctor knew that the patient was 'a more than ordinarily anxious person' and due to her history of anxiety and depression, she would be less able to cope with the embarrassment, discomfort and distress involved in the disruption of her bodily function.[142]

The patient could also refuse to receive information necessary for an informed decision. This is where the patient effectively waives his or her right to receive relevant information and they may waive the right to make decisions. This then goes back to the question of the extent of the doctor's duty to disclose. This may include cases where the patient lacks confidence to analyse the risk data or in some cases would rather depend on their physician's professional information. Again this may be a matter of culture to be respected due to patient autonomy. Otherwise, the doctors should provide some form of information.

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[141] FC, February 8, 1996, unreported.

[142] The Law Review 2007, Puteri Nemie bt Jahn Kassim, *The Reasonable Prudent Patient Test: A Visible Test for this Millenium?* p 613

A doctor must respect the competent adult's right to choose or refuse any particular recommended course of action. A competent adult is generally entitled to reject a specific treatment or all treatment or to select an alternate form of treatment, even if the decision may entail risks as serious as death and may appear mistaken in the eyes of the medical profession or the community. A person has a right to refuse medical treatment even if the refusal leads to his death. This can be seen in the case of *Re B (adult): refusal of Medical Treatment*[143] where a doctor was held liable for not fulfilling the wishes of a 41-year old woman with brain damage who was kept on a ventilator, who wished for it to be discontinued. The doctor here however, refused to do so. The court said:[144]

> "*The right of a competent patient to request the cessation of treatment had to prevail over the natural desire of the medical and nursing profession to try to keep her alive. If mental capacity were not in issue and the patient, having been given relevant information and offered the available options, chose to refuse treatment, that decision had to be respected by the doctors.*"

When a competent patient revokes his or her consent, it must be documented in the medical record.[145]

Under American law, a patient has a prima facie right of self-determination which must be weighed against the interests of four societal interests, that is, preservation of life,

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[143] [2002] All ER 449 Fam Div.

[144] Ibid. p.474

[145] Risk Management Handbook, http://YNHH%20Risk%20Management%20Handbook-

preventing suicide, preserving the integrity of the medical profession and the protection of an innocent third party.

Establishing of capacity arises out of two propositions:

(1) that a doctor ought to respect his patient's autonomy, but

(2) he need only do so when the patient who expresses his will is capable of behaving autonomously.

As stated by Lord Donaldson MR in *Re T (adult: refusal of treatment)*,[146] every adult is presumed to have the capacity to consent, but its presumption can be rebutted. As to patients making the decision to undergo a procedure, the law presumes that a person possesses the requisite mental capacity to make an informed choice.

An example of a scenario is where a young woman whose face had been horribly scarred in an accident, solicited the services of two plastic surgeons. At the same time, there is a mother who is also present in the hospital, whose own daughter was in a persistent vegetative state with no hope of coming out of coma. The mother of the incompetent woman asks the surgeon to remove the facial tissue of her daughter in coma and graft it on to replace the other young woman's burned tissue. This type of surgical procedure creates a controversy on the question of a valid consent on the part of the donee.

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[146] [1992] 4 All ER 649 at 661

Though this may be done in the best interest of the recipient but there remains the biggest concern, of what the recipient will look like upon completion and the likelihood of its success. It is also a question of pressure on the patient to consent to the procedure before he or she fully understands the consequences as otherwise she would be left with a horrible burnt face or scarred.[147] It is easy to imagine a situation where a patient is so despondent and desperate over the physical condition of her face that she would be willing to jump at any chance of improvement, no matter what risk is involved. Thus, the question to consider here is whether the patient is mentally stable to rationally analyze the information provided by the physician. This begs the question whether the patient in this situation can be compared to a reasonable patient. From my point of view the patient will definitely not be able to make a rational decision.

In arriving at a decision of what is in the best interest of the patient, can sometimes be put in striking or emotional terms. It could be weighing the benefits of the treatment against the burden[148].

3.3.2 Incompetent patients

As mentioned in chapter 2 there are difficulties faced by doctors in some cases on how much communication is necessary for an informed consent. This is due to the varying levels of understanding and the capacity of a patient is more or less acute.

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[147] *W... Has First" Face Transplant"* (http://edition.cnn.com/2005/HEALTH/11/30/france.face/; cited

That is why in some cases, the patient's rigid informed consent is not required before a physician proceeds with treatment. In each of these situations, hospitals have developed specific policies and procedures to follow with which all physicians and other health care providers should be familiar. These exceptions include:

a) Emergency treatment

This is where a patient is in immediate need of medical treatment but is unable to give consent because of a physical or mental impairment. Medical treatment can be applied if i) a delay in treatment would be life threatening or cause the patient serious harm; ii) no close family member or surrogate is available to give consent on behalf of the patient; and iii) the physician has no evidence that would suggest that the patient would oppose the treatment. The physician should document in the medical record the emergency circumstances under which the medical treatment without consent was rendered. In *F v West Berkshire Health Authority*[149] it was held that if medical treatment is given in an emergency situation, then there will be a defence to plead necessity in the best interest of the patient.

b) Therapeutic privilege[150]

In rare situations therapeutic privilege can override an obligation to disclose information from the patient in the belief that it would have a harmful effect on the patient. When a physician invokes such a privilege, it is imperative that the objective justification for it be

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[149] [1990] 2 AC 1

documented in the patient's medical record. This was seen in *Dr Ismail Abdullah v Poh Hui Lin*[151] which has been discussed in the previous chapter.[152] This should include the reason why information was withheld, and both the information that was disclosed and not disclosed. It is not acceptable to use this privilege because the patient would be "anxious" or "upset" by the information, or the family does not want the patient told.

c) Lack of Capacity

This occurs in a situation where a person lacks the legal capacity to make certain decisions regarding his or her care. It also includes the case where the patient is a minor. Children are not capable to giving consent as they are deemed to be incompetent. However, this analysis does not apply if the incapacitated individual, while still capable, had articulated treatment wishes prospectively through advance directives, then those directions should be respected.

In England, the law does not equate assessment of capacity with the right decision, the reasonableness of that decision or the rationality of the reasoning process. According to Thorpe J there are three-stage test in *Re C (adult: refusal of medical treatment)*[153] for establishing patient's capacity or competence:

a) Whether the patient comprehended and retained the necessary information;

b) Whether he was able to believe it; and

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[151] [2009] 7 CLJ 167.

[152] p.42.

[153] [1994] 1 All ER 819 (Fam Div) In that case although the patient's general capacity is impaired by

c) Whether he was able to weigh the information, balancing risks and needs, so as to reach a decision?

It is important to note here that the standard of care adopted in *Bolam v Friern Hospital Management Committee*[154] involved a mental patient who was not able to give proper consent as he was unable to comprehend the risk, which was communicated to him. This is why some Commonwealth jurisdictions, like Australia have refused to follow the *Bolam* test.

Children

Laws regarding children have evolved over time. In the United States, they have recognized children's autonomy, including the right to treatment and the right to privacy. Despite this they are considered incompetent without legal capacity to give consent. Parents are the best protectors. A similar position arises in Malaysia. Parental consent must directly benefit the child and is limited to the best interest of the child[155].

In 1986, the position took a turn in the United Kingdom where it extended some autonomy to children after the case of *Gillick v West Norfolk and Wisbech Area Health Authority*[156]. This issue has been under controversy. It was about a decision of a doctor prescribing contraceptive treatment to an underage girl without the consent of her

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[154] [1957] 1 WLR 582.

[155] s2(1) of the Child Act 2001 defines a child as a person below 18.

parents. The doctor argued that he merely acted in the best interest of the girl whom he felt had sufficient understanding and intelligence, which enabled her to make decisions. Though the court argued that teenage pregnancies would increase if the courts ruled that parental consent was necessary, on the other hand the judges also felt this would encourage under-age sex if they did not.

Even twenty years later, the ability of those under 16 years of age to seek confidential medical advice and abortion was again challenged in the court in *R v (ota Axon) v Secretary of State for Health*[157] where it was said to be ironic and not acceptable now to retreat from the approach adopted in *Gillick* and to impose additional new duties on medical professionals to disclose information to parents of their younger patients. Thus, a very high maturity and understanding is pertinent in this case.

Basically, the age of majority in the United Kingdom is eighteen,[158] but by virtue of s.8, a sixteen year-old can give a valid consent to treatment.[159] Sir Stephen Brown in *Re L (medical treatment: Gillick competency)*[160] decided whether a fourteen-year old girl actually understood what was involved in her decision rather than whether she was capable of understanding it. Lack of understanding demonstrates the inability to understand. However, Parliament adopted the test that a child should be 'capable' of understanding, but guidance under the legislation is still lacking.

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[157] [2006] EWHC 372

[158] s.1 Family Law Reform Act 1969

[159] Family Law Act 1969

The issue of best interest was discussed in the case of *Airedale NHS Trust v Bland*[161] where the patient by being permanently insensate has no interests in the treatment being continued. Reference was also made to the unfortunate decision of *Re A (Children) (Conjoined Twins: Surgical Separation).*[162]

An NHS Trust v MB & Anor[163] was another case where the National Health Service Trust argued that the condition of the 18 month old was in steep decline and that his best interest's lay in withdrawal of ventilation to allow a dignified death. Mr Justice Holman explicitly stated that the decision required was not a matter of ethics but a consideration of the best interests of the child. Balancing the evidence before him he stated that, the ventilation should not currently be withdrawn, given among other factors, the possible cognitive functions of MB and his bond with parents and siblings. However, he then declared that the doctors could lawfully withhold or not administer four other procedures.

The question also arises whether parental consent could be waived in some circumstances, and if so would it be to the detriment of the child. Comparatively, the position of minors in Malaysia is governed by statute where parental or guardian's consent is required for health treatments.[164] The Court for Children have taken a very

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[161] [1993] 1 All ER 821

[162] [2001] Fam 147.

[163] [2006] EWHC 507 (Fam). An 18 months old, had been diagnosed with spinal muscular atrophy, a genetic condition that gradually removes the ability to moves muscles voluntarily. He was suffering from the most severe form of the condition and by the time of the hearing could only move his eyebrows to indicate pleasure or pain.

paternalistic approach and decisions are based on the welfare of the child which are of paramount importance. However, the Malaysian *Child Act 2001* is silent on the issue of the wishes of the child, unlike the provisions of the *Children Act 1989* in the United Kingdom. In Malaysia, the question of what is in the child's best interest[165] should be determined and the welfare of the child should be clearly defined.

Minors are allowed to get married with the consent of their parents once they are over the age of 16, which places a huge amount of responsibility on them in decision-making to their new beginning. That being the case, such a decision-making process should be extended to medical treatment depending on the maturity and understanding of the child.

Recent developments along this area is that of best interest versus substituted judgment. The 'substituted judgment' has been employed by some American Courts as an alternative to the best interest test. Under the Substituted judgment test the decision is to be the one that would be made by the mentally incompetent person as if she were mentally competent. The test requires the application of the subjective values of the individual insofar as they can be known. An attempt must be made to ascertain the actual preference for or against matters such as decisions about the use and removal of life support systems, blood transfusions, organs transplantation, or euthanasia. To date substituted judgment does not apply in Malaysia.

3.4 Consent Forms

Consent forms act as an important tool to reduce litigation, which would be to the advantage to the doctor and hospital. Merely signing a consent form is not enough if the patient fails to understand the nature of the treatment. The role of such documentation is a formal process of informed consent, which helps in the process of communication, though depending on the method and manner of its implementation.

Since consent forms are given to patients to sign prior to a surgery, there is also concern on the effective communications and procedures used to obtain such consent from some category of patients such as the elderly. This means, whether there is sufficient substance contained in the consent form. The question remains as to how many patients would have understood the consent form and how do they perceive consent in such instance. In the event the facts are not made known to the patient, then the consent is not an informed one. The consent form may be too long, difficult and complex to understand. A sample of a consent form can be seen in Appendix 2.

This form cannot substitute the process of risk disclosure. In some cases it may be proposed for such a form to be given with optional appendixes detailing all the pertinent information. Then it would be up to the individual patient to decide of surgery.

Where a patient did not sign a consent form prior to surgery, the patient should never be made to sign anything after the surgery, as "retrospective" consent is ineffective.

It is much preferable to obtain documentation of the consent prior to treatment. However, presuming that the physician has discussed the surgery with the patient prior to treatment, documentation by the responsible physician of that discussion in the medical record may be acceptable under hospital policy in some countries. If the patient signs a form after treatment, the physician must document that fact and that the patient was awake, alert and aware of the circumstances.

Due to the complexities, a substantial overhaul of the present system of the doctrine of informed consent should be considered. There is a need to search for a single test of competency, which should be recognized. For instance a shared decision-making[166] may serve to be useful as it satisfies the patients' desire for more information and inclusion as well as to improve their overall well-being.

CHAPTER 4

INTERVIEWS WITH PHYSICIANS AND PATIENTS

4.1 Introduction

There may seem to be hidden difficulties within the legal framework of informed consent, which are potential legal risks to the provider. There are no easy answers since communication continues to be an obstacle in doctor-patient relationship as discussed in chapters 2 and 3. This chapter will present the findings on the attitudes of medical practitioners and patients on the consent process, obtained through interviews.

Interviews were carried out at both the public and private hospitals in February 2009, to explore how patients understood the workings of the medical paternalism in a clinical setting that is, consent. In order to gain access to the public hospital, details of the proposed research was submitted for scrutiny by the author to the Medical Ethics Committee for example to the Universiti Hospital. Besides that the author had the liberty of interviewing her own doctor.

4.2 Participants

The interviews were restricted to physicians and patients. The participants were either receiving treatment or had received treatment. There were six males and five females. There was preparation of questionnaires with pre-determined set of questions designed to interview doctors and patients in order to demonstrate the effectiveness of the doctrine in practice. Sampling of respondents was by using convenient technique. All respondents were given the assurance that their participations would remain confidential.

4.2.1 Physicians

Four physicians participated in this survey. The fifth participant was suddenly called to attend to an emergency matter when the meeting was scheduled to have taken place while one declined to take part due to heavy schedule.

The author explained to the physicians the objective of this study. The respondents specialized in a range of areas such as a Senior Consultant Pediatrician, Obstetrician and Gynecologist and Gastroenterologist. Almost without hesitation some of them were more than willing to participate. The questionnaire consisted of twelve general questions, which is attached as Appendix 3. They were questioned on their treatment practices and dealing with patients. The duration of each structured interview was approximately twenty minutes.

4.2.2 Patients

The Pusat Perubatan Universiti Malaya gave ethical clearance on 21 January 2009, and subsequent to that the following interviews were conducted.

In this case the total samples of patients of seven included two minors and five adults. Two other patients were quiet when approached. Initial approach was made very subtly where the author started a normal conversation with the patient. The average duration of the interview lasted for about half an hour. Some of them included out-patients which made it much easier to start a conversation with.

The questionnaire consisted of two sections: general and personal details. Under the first part they were asked how much information they were given and whether it was sufficient. A copy of it is attached as Appendix 4. There was also an area on consent forms. Patients were asked if the contents of the consent forms were explained to them properly.

The analysis does not attempt to correlate each group's responses. Those who participated will be dealt according to the age cohort below.

i) Minors

The two minors involved were a twelve-year-old boy and a fourteen-year-old girl. The boy had been admitted for appendicitis while the girl for severe food poisoning. The parents were kind enough to share their thoughts. Since it was a

very informal conversation the participants were rather comfortable about the whole process.

ii) Adults

The patients were between thirty to seventy years of age. One was a case where the patient had stones in his kidney, the second being a patient who had had a spinal surgery, a third was with regards to a lump in the patient's breast and the last one who was involved in an accident.

iii) Elderly

Only one elderly patient who was above eighty years of age was available.

Below is the demographic breakdown of the said patients:

(a) age groups of patients

Age group	Total patients	Percentage
10-19	2	28.5
31-40	1	14.2
41-50	2	28.5
61-70	1	14.2
71 and above	1	14.2

(b) Education level of patients

Education level	Number of patients	Percentage
Schooling	2	28.5
STPM	1	14.2
Degree/ Diploma	3	42.8
Housewife	1	14.2

(c) Sex of patients

Sex	Number of patients	Percentage
Male	2	28.5
Female	5	71.4

4.3 Interviews with patients

There is no doubt that six of the patients seemed generally satisfied with the consultations and have a good relationship with their doctors. Only one felt awkward when it came to stressing her problems to her doctor due to her conservative attitude. However, one participant did indicate that he felt comfortable with a senior doctor as compared to a younger one. Besides that, there were other findings of this research which included as follows:

a) Patients willing to receive information

The seven patients were generally enthusiastic about receiving information and to be kept informed. In other words most of them wanted to know the risks involved. One patient was asked what he wanted his doctor to tell him, and his reply was "everything". He claimed that the doctor should be honest to the patient.

Generally most of the patients did not have any complain about the way in which they were being treated. Some even replied that they would leave it in "God's hands". In this study, the parent of the twelve-year-old child revealed that when her child was brought in for severe abdominal pain, she was initially told that her child had appendicitis but they did not operate on her child. Instead, the doctor had decided to do more tests and only confirmed a day later that it was mere urinary infection. The parents of the child had no problems accepting the explanation to this second diagnosis. It was the consent of the parents that was required to treat the child. There is concern as the frequency of misdiagnosis in practice, as in the present case. It was fortunate enough that the child was not operated after the first diagnosis was made.

b) Communication and Understanding the information given

Terms explained	Number of patients	Percentage
Understood	5	71.4
Did not understand	2	28.5

All the participants received information. Communication is needed in a doctor and patient relationship and the consent process. As to the understanding of the diagnosis and treatment, though most patients especially those with some qualifications felt it was not a problem but they still felt it was difficult to comprehend that information *at the time*[167] when it was given. As one patient put it, "I was listening attentively to what the doctor was saying until he told me that I had stones in my kidney, I just went numb and felt my heart beat faster. At that moment I thought of the worst and didn't know what they were talking anymore and I merely stared at them". Obviously the fright that the patient gets, puts them preoccupied in their own thoughts. As such it is doubtful that the current participant would have fully been informed in the proper context of consenting to the treatment.

Only about 42.8% were less than "very satisfied" with the information given. The reason being that some felt that they were not told the recovery time after treatment or how they would feel after that. Another factor was with regard the time spent by the doctor giving the necessary information. Majority claimed it was less than fifteen minutes. As for the patient who is in her 30s said that when a mammogram was conducted on her, she was not informed properly as to the extent of the pain. She commented that the pain lasted in both breasts up to four days before gradually subsiding. Anyway she was to have the lump removed when this study was done. A recent article in the newspaper[168] highlighted the problem of communication skills among government doctors and government clinics.

Doctors being skilled persons know how to relay information and explain it in a manner proper to the patient. The elderly patient in this study, though competent, had problems understanding and communicating with her doctor due to language barrier. She communicated in Bahasa Melayu but was not proficient in it, which, made things more complex on both parties. She was diagnosed with pneumonia. She claimed that the doctor merely told her what he was going to do but she did not understand why he was doing it. Sometimes she had some family members to interpret and explain to her the information given. The danger lies to the extent to which this information is correctly translated and explained to her. There could be some distortion by the time the message gets to her in her dialect. This raises the issue of the effectiveness of her consent to the treatment she received. When asked how much she understood what the doctor said, she merely shook her head and said the doctor was a very nice person and should know what he is doing. At that point it may seem that she did not want to know anything about any risks involved but merely to get better. In such cases the danger lies if a doctor underestimates the patient's comprehension.

As for the author's physician, he would always explain matters to her in a very clear and precise manner and would repeat if a patient did not understand certain terms. This could contributed to the fact that it is a private practice and the doctor has to ensure clarity of information to patients.

The findings of this study indicate that openness between doctors and patients is not totally evident in every single case. There is no shared decision-making. Some patients

may become unduly anxious and their preferences differ in information disclosure. Not all want to know everything all the time. It defers from patient to patient and there is a need to discuss the benefits of the treatment with the patient and in particular attention should be given to the consequences of not wanting to know.

Understanding information is not a matter of intelligence as it is a matter as to how much a patient can absorb so as to then give his or her consent. As such it would be proper for disclosure to be made both orally and in writing. The risk communication should be worded as simple as possible and involve a two-way exchange of opinions. Otherwise it may be a case where both the doctor and patient would seem to have different objectives in mind and the goals of communication would be destroyed. Probably a professional interpreter would also be a helpful for patients who have language problems when such information is being conveyed to the patient. As for the case of mammogram, it appears that even leaflets do not warn women adequately the uncomfortable process, which is encountered.

c) *Consenting to the treatment*

Majority of participants gave their consent while some had discussed with friends and family members before receiving treatment. About 28.5% thought that consent was something they had to agree in order to be treated, while 71.4% knew it was about their right to self-determination. The degree of knowledge culpable of making consent would be rebutted if the patient giving the consent was not aware of the full implications of consent. This was seen in the case of the elderly participant as well as one of the parents

of the child who had not understood fully the inherent risk which was be involved. She basically thought of it as making her better.

In another incident, one of the participant in this study fell within the criteria of paternalism where he was hurt as a result of being attacked by "Mat Rempits". He was slashed on his knee and hand with a 'parang'. Being in a state of shock, he was rushed to the hospital where he was wheeled into the operating room as it was a case of emergency. According to him, at that time he vaguely remembers of being told as to what they were going to do. Due to the excruciating pain he was unable to remember much. At that moment, he did not care what they were going to do as long as they could stop the pain and save his leg. In cases of emergency, the hospital has specific policies and procedures, which are to be in the patient's best interest. Here, the participant was in immediate need of medical treatment but was unable to give consent because of a physical impairment and any delay in treatment would be threatening. As such the treatment was carried out without his proper consent.

(d) Consent Forms

Consent from patients are normally obtained a day before the surgery. The substantive part of the consent forms are quite similar in government and private hospitals. Only two participants had significance to the consent form. One was the man in his 50s who had undergone a surgery, where he was asked to sign both the consent form for the surgery as well as for the anesthetic to be applied. The other was the woman who was to have a lump in her breast removed. When the man was asked whether he knew that the form was

called a "Consent Form" his reply was that he had signed a piece of paper but was not sure what it was called. The participant claimed that both the surgeon and the anesthetist had come to see him the night before the surgery to explain the nature of the surgery, the risks involved and the risk of the anesthetic to be administered during the surgery. He was allowed to ask questions. Later he was given the form. When signing the consent form he realized that whatever communication that had taken place earlier was not reflected in the said form. In fact it looked rather complex and did bother reading it in detail.

As for the woman, being a little shaken about having to go through the operation, was not able to recall exactly when she had signed the consent form but did remember signing something a day earlier when the head nurse approached her which was relating to the surgery.

As for the two children in this study who were unable to make a decision in relation to their health, the parents were asked to sign the consent form for the children to be treated. A copy of the said form is attached as Appendix 6.

The findings show the patients poor recollection of the significant aspects towards the consent form. The issue of language on the consent form may aggravate matters in determining the level of the patient's understanding. Some patients view a consent form as something necessary for them to get treated. Only one participant had problem understanding the form for treatment, which was both in the Malay and English

languages. Her relatives explained it to her, which raises a concern about the accuracy of the information being given to her as to allow her to understand the nature of the risks, if any. Thus, there is an urgent need for consent forms to also be in other languages. Another point to be noted is that, all these consent forms merely state the date when the consent is obtained but does not indicate the time when it is obtained. It would be useful to incorporate the time as it will indicate when the patient's intention of making a decision at his or her own free will arose. Probably a copy of the consent form should also be given to the patients once they have signed it. Apart from that, it is apparent that the consent form does not indicate the type of anesthetic used.

4.4 Interviews with doctors

All four physicians had more than ten years standing in their area of practice and they all agreed on the need to have a doctor and patient relationship. They also agreed the importance of informing patients of their diagnostic and proposed treatment. However, they did not deny the fact that there are few patients who encountered some difficulty in understanding the information given due to language barriers. In other words when the information is translated it may cause problems as that information may differ and not reflect what the doctor had said, especially when the translator is a member of the family who may decide what and how much to relate. This also goes for the explanation given on the consent form.

Three physicians agreed that there are some patients, though few, who want the doctor to choose their treatment option. They would say to the doctor, "Doctor what do you think I should do? You decide." This could be contributed to the fact that a patient may feel comfortable with a senior doctor or has been a patient of the doctor for years. As it is not the duty of the doctors to decide for the patient they would then speak to the family members to make a decision as being the best substitute.

However, two doctors indicated the problem of some patients not wanting to be treated by hospitals despite being admitted, as they preferred the medicine man. This also applied to children where they may not get the proper treatment at the hospital due to the parent's interruption on traditional beliefs. There were instances when a parent of a sick child would take the child out of the hospital despite being told not to do so. The physicians agreed that parents are legally responsible for the child and that the needs and wishes of the parents have to be abided to. Therefore, in such cases the hospital now gets the parents to sign a form known as the "*at own risk*"[169] consent form. This is to avoid any form of liability against the hospital in the event of adverse effect as a result of this act. However, from the interviews conducted pertaining to the above issue, it appears to be more rampant in the government hospitals as opposed to the private.

In fact the doctors from the private hospital indicated the types of patients also mattered, that is, whether they are locals or foreigners. According to them foreign patients seem more receptive to information given. Besides they would ask more questions as opposed to locals.

Only two of the participants agreed that there is a need to improve the consent process. This was namely in the private hospitals where there is concern of impending legal suit when patients stress lack of knowledge. The physicians felt that communication is crucial by both parties in order to ascertain the ability of the patient's understanding. Besides that, it was noted that some doctors especially in the private practice, have resorted to some extent to defensive medicine as they ask their patients to undergo a series of tests, which are not only expensive, but may sometimes result in false positive results.

As to the issue of the patient's best interest, they all agreed that it is important to preserve patient's autonomy but it is a very difficult situation since they have to ensure what they do is the right thing at that very moment of time.

CHAPTER 5

CONCLUSION

This research study has examined the perception of the adequacy of the doctrine of informed consent in law and in practice. Being a small study it is difficult to generalize the findings. It however demonstrates that the legal concept of informed consent is at odds with the medical practice and autonomy rights.

This research has provided the insight into the way in which some patients perceive the consent process and how this relates to the law. The findings have shown that patients of public and private hospitals do actually prefer to be kept informed about the risks and benefits of the treatment. Doctors and patients may have different expectations on the process and do not engage in shared decision-making. Information may either be given and understood or not properly understood by the patient as seen in the research. The word 'informed' seems misleading and less satisfactory in practice.

With the existing problems, there is a need to make improvements. One way is by creating awareness in patients by providing them with necessary information in order for them to make an informed decision. Another way is to encourage patients to ask questions so as to improve communication, which will benefit both in negotiating treatment decisions. Perhaps an average patient would feel more encouraged to ask questions about any lingering doubts that might be on his or her mind about the proposed treatment if he or she feels that their concerns will be taken seriously and their fears

allied. This atmosphere needs to be provided to the patient by the intending physician. It follows therefore that the doctor's communication skills is vital for these exchange of ideas. This will of course create a shared decision-making, which will preserve the right of autonomy of the patient by the patient-based standard. As such we could have both physicians and counselors, given that time is of essence to physicians, to assist patients to identify their personal values relevant to the treatment decision. This should also apply to parents who play an important role in relation to the medical treatment to their children instead of it.

With regards to the consent form, since patients participation is important in making decision, they should be encouraged to view the consent form in detail instead of merely taking it to be a piece of paper they were signing for the surgery as a mere formality. Being a multi-racial country, it is about time that such consent forms to be available in all languages, such as, Malay, English, Chinese, Tamil and Punjabi.

However, implementations will be challenging but not impossible. It is a matter of determination to improve the medical practice and the way the law addresses it. The government too should play a major role in ensuring that patients' interests are safeguarded. This could be done by creating awareness to the public by having advertisements, leaflet distributed and by holding public health seminars on the importance of patients' autonomy in decision-making process which would also highlight the purposes of a consent form.[170]

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[170] Recently, the Health Ministry has launched a theme "*Kami Sedia Membantu*" to eliminate complaints [illegible] communication skills course. See Appendix 5.

In conclusion, there still remains some complexity and uncertainties in the law with regards balancing the rights of the patient and the doctor in practice. Though the doctrine of informed consent may seem to be a well-established theory, it may not always be established in practice both in Malaysia and most parts of the world.

Obtaining consent is not merely a procedure or process that is satisfied or fulfilled merely through form-filling or the appearance of doctor-patient consultation. There are other factors, which are crucial to the obtainment of consent. Both the doctor and patient need to be able to identify all the relevant factors surrounding the treatment, for example clinical diagnosis and risks, the patients fears regarding both health and financial matters and many others, before arriving at a decision which is clinically practical and is in the best interest of the patient. Perhaps in such a caring medical environment, taking into account existing constraints, the gap between obtaining consent as a mere 'form and procedure' and obtaining consent as respect and care to the patient, will be narrowed.

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Woman Has First" Face Transplant"

NEWSPAPER ARTICLES

"Prison officer files RM2m suit over botched delivery." *TheSun.* Wednesday, May 14, 2008.

"I last saw my wife alive before tummy tuck." *News Straits Times*, Thursday, July 24, 2008.

"Hospital sued over husband's death". *News Straits Times.* Saturday, March 7 2009

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APPENDIX I

NEW STRAITS TIMES THURSDAY, JULY 24, 2008

'I last saw my wife alive before tummy tuck'

■ By Sushma Veera
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KUALA LUMPUR: "We kissed and I assured her that everything was going to be okay before she went into the operating theatre. I never thought that it would be the last time we would speak with each other."

A distraught Matthew Scott Oakley Abdullah broke down in court yesterday as he recalled the last moments with his wife.

With tears flowing, Oakley told High Court judge Datuk Tengku Maimun Tuan Mat how he lost his wife, Nik Rosemawati Nik Mohamed, 43, following an operation.

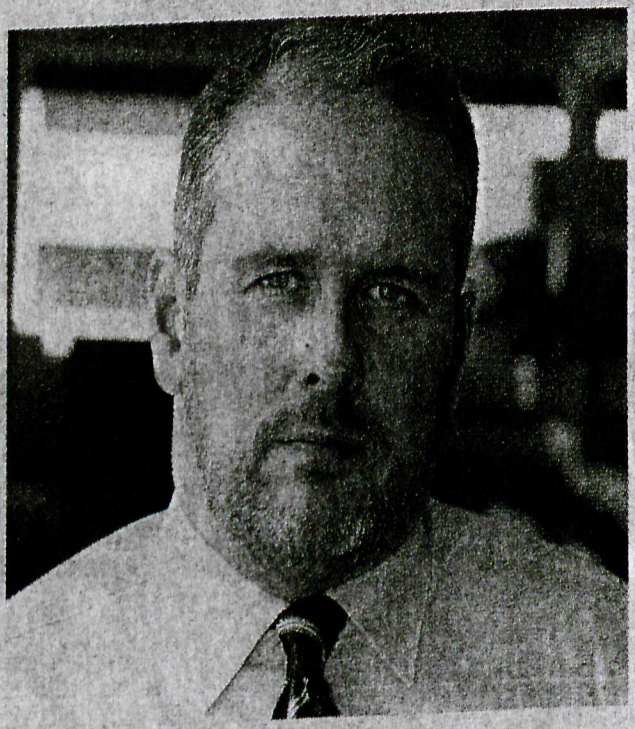
He cried again when he told the court of how he was by Nik Rosemawati's bedside at the Intensive Care Unit when various alarms from the monitors started to go off.

The doctor later informed him that his wife had died.

Oakley, a civil engineer from the United Kingdom was testifying against plastic surgeon Dr George Varughese and anaesthetist Dr R. Raja Kumar.

In his suit filed on June 10, 2006, Oakley, among others, claimed that the two doctors had failed to use reasonable care and skill in monitoring and assessing his wife's condition.

He is claiming RM520,431 for general and special damages, apart from interest,



Matthew Scott Oakley Abdullah was by his wife's side at the hospital before she died.

move fatty tissue around her abdomen, which developed after her second pregnancy.

"She was concerned over the large amount of fatty tissue as well as excess skin hanging around her waist."

To a question by his counsel, Renu Zechariah, Oakley said Dr Varughese recommended a full tummy tuck which included liposuction and corrective surgery to remove the fat and skin.

The couple was informed that it would cost about RM9,000.

He also offered the Oakleys staggered payment over six months.

Oakley said Dr Varughese told Nik Rosemawati that the surgery was a simple procedure requiring two or three small incisions.

"Dr Varughese also suggested that my wife be sedated and that he would be using local anaesthetic to ensure that she did not feel anything."

Oakley, who has since moved to Dubai with his two children, Sarah Rose, 9, and Daniel Adam, 6, said that the doctor was fully apprised of

went for the operation.

"Dr Raja was in attendance and had administered the anaesthetic on my wife during the operation."

He said that at 6.30pm, Dr Varughese had informed him that the operation was successful.

"However, about 7.10pm, I was told that my wife had suffered a cardiac arrest and that resuscitation procedures were undertaken. My wife was then put on a ventilator."

Oakley said arrangements were then made about 11pm to transfer Nik Rosemawati to the Gleneagles Intan Medical Centre.

"Nik Rosemawati was at the ICU for two days where her condition continued to deteriorate and she died on June 23, 2004, without regaining consciousness."

In his statement of claim, Oakley said the post-mortem report revealed that his wife had suffered extensive internal bleeding and the cause of death was stated as "Acute Intraabdominal Injury (Perioperative Death)".

In their statements of defence, Dr Varughese and Dr Raja denied negligence.

Dr Varughese argued that at all times, he had acted with the skill and diligence expected of a medical practitioner, while Dr Raja claimed that the injury suffered by the deceased was due to the abdominal liposuction carried out by Dr Varughese and did not have any con-

APPENDIX 2.

news without borders

Prison officer files RM2m suit over botched delivery

by **Maria J. Dass**
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SHAH ALAM: A prisons officer yesterday filed a RM2 million suit against a doctor and the government for negligence following the death of her newborn son, allegedly because of a botched ventouse delivery (using vacuum).

Noor Hidayu Hashim, 21, who named medical officer Dr Wan Shahruliza Shaharan, the director of Kajang Hospital and the government as the respondents, is claiming RM1,850 in special damages, RM500,000 in general damages, RM1 million in exemplary damages, RM500,000 in aggravated damages, cost and other cost deemed fit by the court.

In her writ of claim, Noor Hidayu said she went into labour at 3am on April 4 and was taken to Kajang Hospital by her husband.

At about 9am the same day, Wan Shahruliza examined her and found that her cervical opening had dilated by 3cm.

Noor Hidayu claimed she repeatedly told Wan Shahruliza she was having stomach pains and that her water bag (amniotic sac) had burst, but was told by the doctor this was a normal occurrence for someone in labour and stressed that the plaintiff and her baby were in good health.

Noor Hidayu then attempted to deliver her baby normally with the assistance of Wan

The plaintiff gave birth to a 4.75kg baby boy at 6pm and was later informed that the child had some complications and had to be taken to the hospital's intensive care unit.

At 9.30pm, a hospital staff by the name of Zanariah Rohana informed Noor Hidayu the baby had died.

She said using an X-ray film, Zanariah had showed her the image which showed that the baby's shoulders had been broken (shoulder dystocia), while the skull was fractured and the child had lost a lot of blood due to the method of delivery.

Zanariah further said the method of delivery was also cited as the cause of death in the medical officer's report on cause of death (*Perakuan Pegawai Perubatan Mengenai Sebab-Sebab Kematian*).

In the writ, Noor Hidayu, who was discharged on April 12, stressed that Wan Shahruliza's diagnosis were wrong and that the injuries to the baby was caused wholly and/or jointly by the negligence of the defendants.

Among the details of negligence she cited were:

» failure to conduct a thorough and proper check on the baby's size and condition;

» failure to make the necessary preparations to face possible complications from delivering a baby born to someone like her who was diabetic;

» failure to immediately treat her although her water bag had burst for over eight hours;

» failure to ensure that proper treatment and

APPENDIX 2

Hospital sued over husband's death

KUALA LUMPUR: A housewife and her four children yesterday filed a suit against Hospital Pusrawi and two of its doctors for negligence.

Norhayati Ayob, 50, Siti Maisarah Abdul Latif, 21, and Siti Hasanah, 20, claimed that their negligence had caused the death of Norhayati's husband, Abdul Latif Othman, 49.

Norhayati also filed the suit on behalf of her two other children — Muhammad Hatim, 17, and Siti Mahirah, 13.

They named Hospital Pusrawi Sdn Bhd as the first defendant and Dr Ainy Md Aris and Dr Didi Indra Tjahya as the second and third defendants respectively.

The plaintiffs claimed the defendants were negligent in treating Latif who was admitted to the hospital on March 3, 2006, for surgery to treat an abscess on the leg.

He allegedly suffered complications and died several days later.

EW STRAITS TIMES SATURDAY, MARCH 7, 2009

APPENDIX 3

CONSENT BY PATIENT FOR CLINICAL RESEARCH *FACULTY OF DENTISTRY, UM, K.L.*

I, ... Identity Card No. .....
(Name of patient)

of..... *(Address)*

hereby agree to take part in the clinical research (clinical study) specified below :

Title of Study : .....

the nature and purpose of which has been explained to me by Dr..... *(Name & designation of doctor)*

and interpreted by..... *(Name & designation of interpreter)* to the best of his/her ability in.....

language/dialect.

I have been told about the nature of the clinical research in terms of methodology, possible adverse effects and complications (as per the patient information sheet). After knowing and understanding all the possible advantages and disadvantages of this clinical research, I voluntarily consent of my own free will to participate in the clinical research specified above.

I understand that I can withdraw from this clinical research at any time without assigning my reason whatsoever and in such a situation shall not be denied the benefits of usual treatment by the attending doctors.

Date .....

Signature or thumbprint..... *(Patient)*

IN THE PRESENCE OF

Name .....

I/C No. .....

Signature ..... *(Witness for signature of patient)*

Designation .....

I confirm that I have explained to the patient the nature and purpose of the above mentioned clinical research.

Date .....

Signature ..... *(Attending doctor)*

CONSENT BY PATIENT
FOR
CLINICAL RESEARCH

R.N.
Name
Sex
Age
Unit

APPENDIX 4

DOCTOR'S OPINION ON INFORMED CONSENT

PLEASE TICK YOUR ANSWER IN THE APPROPRIATE BOXES

1. Are your patients informed of their diagnostics and the proposed treatments?

Always ☐ Sometimes ☐ Depends on circumstances ☐ Never ☐

2. Do your patients encounter any difficulties in understanding the nature of the proposed treatment?

Always ☐ Sometimes ☐ Never ☐

3. In such cases are they willing to receive such information?

Yes ☐ No ☐

4. Are the patients informed of all risks or complications or side effects, which are inherent to the recommended treatment?

Always ☐ Seldom ☐ Never ☐

5. Are your patients informed of any other options available to the said treatment?

Always ☐ Seldom ☐ Never ☐

6. Do they consent to the said treatment willingly?

Always ☐ Seldom ☐ Never ☐

7. Are the patients informed as to the contents of the Consent Form adequately before they sign it?

Always ☐ Seldom ☐ Never ☐

8. Do they encounter any language barrier in such forms?

Always ☐ Seldom ☐ Never ☐

9. Do you think that the relationship between a doctor and patient is very important in the medical profession?

Yes ☐ No ☐

10. In your opinion is there a need to improve on the consent process?

Yes ☐ No ☐

11. How do you administer such information if a patient is a child?

.....

12. How would you decide what is in the best interest of a patient?

.....

13. How long have you been in this area of specialization?

Less than 5 years ☐ Between 5 – 10 years ☐ More than 10 years ☐

...held in strict confidence

APPENDIX 5

PATIENT'S OPINION ON INFORMED CONSENT

PLEASE TICK YOUR ANSWER IN THE APPROPRIATE BOXES

A. GENERAL

1. Do you have a good relationship with your doctor?

Yes ☐ No ☐

2. Did your doctor explain the facts of treatment adequately to you?

Yes ☐ No ☐

3. Did you understand those terms explained by your doctor?

Yes ☐ No ☐

4. Were you satisfied with the explanation?

Not satisfied ☐ Very satisfied ☐ Satisfied ☐

5. Were you informed of any other options available to the said treatment?

Yes ☐ No ☐

6. Were you willing to receive the said information provided by your doctor?

Yes ☐ No ☐

7. Did you consent to the treatment?

Yes ☐ No ☐

8. Were you asked to sign any consent form?

Yes ☐ No ☐

9. If so, did you have any trouble understanding the contents of the consent form?

Yes ☐ No ☐

10. If the answer to above is yes, what was the main problem with regards to the consent form?

Language barrier ☐ Too complex ☐ Not explained ☐

B. YOUR PERSONAL DATA

1. Into which of the following is your age categorized under?

10 – 19	20 – 30	31 – 40	41- 50	51 –60	61-70	70 -80
☐	☐	☐	☐	☐	☐	☐

2. Which of the following describes your level of education?

Diploma	Graduate	Professional	Others
☐	☐	☐	☐

3. Your sex — Male ☐ Female ☐

4. Marital status — Married ☐ Single ☐

5. Your race — Malay ☐ Chinese ☐ Indian ☐ Others ☐

All information contained herein will be regarded in strict confidence

THANK YOU VERY MUCH FOR YOUR COOPERATION AND UNDERSTANDING

APPENDIX 6

theSun | TUESDAY FEBRUARY 24 2009

Docs who do not communicate top complaints

PUTRAJAYA: Lack of communications skills among government doctors and nurses in hospitals and government clinics top the list of complaints from patients.

Health Minister Datuk Seri Liow Tiong Lai said yesterday he was informed that 34 complaints had been received by the Public Complaints Bureau since January, pertaining to communications or the lack of it from doctors and nurses.

"Some doctors speak very little, some hardly speak to patients. Doctors must have good interaction skills with patients because some may require more than just medical treatment," he told reporters after opening a Corporate Culture campaign yesterday.

Liow, who also launched the ministry's logo and new theme *"Kami Sedia Membantu"*, hoped the new approach and initiative would help eliminate future complaints. He said the ministry

APPENDIX 7

CONSENT BY RESPONSIBLE RELATIVE FOR OP/TREATMENT PUSAT PERUBATAN, U.M.,K.L.

I, ... Identity Card Number .....

of .....
(Address)

hereby consent to the submission of .....
(Name of Patient)

to undergo the *operation/treatment/procedure of .....

the nature, purpose, effect and risks of which have been explained to me by Dr. ..... through the interpretation of .....
(Name of Attending Doctor) *(Name of Interpreter)*

who has, to the best of *his/her ability, truly, distinctly and audibly translated the aforesaid nature, purpose, effect and risks to me in ..... *language/dialect.

I also consent to the submission of the above patient to such further or alternative operative measures or treatment or procedures as may be found necessary during the course of the *operation/treatment/procedures and to the administration of drugs and local anaesthesia and to any tests as may be appropriate. I further consent to any disposition deemed proper by the staff of the University Malaya Medical Centre of the parts and tissues removed in the process of performing such procedures. I further understand that all such *operation/treatment/procedures are subject to their own risks.

No assurance has been given to me that the *operation/treatment/procedures will be performed or administered by any particular doctor.

Date ..... Relationship to Patient ..... Signature or Thumbprint .....

IN THE PRESENCE OF

Name .....)
)
Identity Card No. .....)
)
Designation .....)

Signature .....
(Witness for Signature of Responsible Relative)

I confirm that I have explained to the relative the nature, purpose, effect and risks of the above-mentioned *operation/treatment/procedures. In my opinion *he/she understood this explanation.

Date .....

Signature .....
(Attending Doctor)

*strike out where applicable

CONSENT BY RESPONSIBLE RELATIVE	R.N. Name

APPENDIX 7

ONSENT BY RESPONSIBLE RELATIVE FOR ADMIN. OF ANAESTHESIA PUSAT PERUBATAN, U.M.,K.L.

I, ... Identity Card Number .....

of .....
(Address)

hereby consent to the submission of .....
(Name of Patient)

to undergo the administration of such anaesthesia as may be considered by the anaesthesiologist to be necessary or advisable the nature, purpose, risks and effect which have been explained to me by

Dr. ..... through the interpretation of .....
(Name of Attending Doctor) *(Name of Interpreter)*

who has, to the best of *his/her ability, truly, distinctly and audibly translated the aforesaid nature, purpose, effect and risks to me in ..... *language/dialect.

I also consent to the submission of the above patient to such further or alternative procedures as may be found necessary during the course of the administration of anaesthesia and to the administration of drugs and any tests as may be appropriate.

No assurance has been given to me that the anaesthesia will be performed or administered by any particular doctor.

Date ..... Relationship to Patient ..... Signature or Thumbprint .....

IN THE PRESENCE OF

Name .....)
) Signature .....
Identity Card No. .....) *(Witness for Signature of Responsible Relative)*
)
Designation .....)

I confirm that I have explained to the relative the nature, purpose, effect and risks of the above-mentioned anaesthesia. In my opinion *he/she understood this explanation.

Date ..... Signature .....
(Attending Doctor)

*(strike out where applicable)

BK-MIS-121-E01

R.N.